

**PUBLIC HEALTH RELATED TRIPS FLEXIBILITIES AND SOUTH-SOUTH
CO-OPERATION AS ENABLERS OF TREATMENT ACCESS IN EASTERN AND
SOUTHERN AFRICA:**

PERSPECTIVES FROM PRODUCING AND IMPORTING COUNTRIES

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Statement of Originality

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Abstract

Eastern and southern Africa, a region that is home to a twentieth of the world's population, accounts for half the number of people living with HIV globally, including an increasingly drug resistant Tuberculosis epidemic. The high mortality and untold human suffering associated with HIV in the region during the late 1990s and early 2000s has mostly been mitigated by a rapid scale up of national HIV treatment programmes over the past decade, largely made possible by generic competition from Indian pharmaceutical manufacturers.

The sustainability of treatment programmes in the region depends on various factors. National HIV treatment programmes are largely financed by multilateral donor mechanisms which are facing a decline in funding for the first time in the history of the AIDS response. Indian pharmaceutical manufacturers are increasingly encountering patent barriers stemming from the country's implementation of its intellectual property obligations under the World Trade Organisation's TRIPS Agreement. As eastern and southern African countries increasingly focus on local pharmaceutical production and south-south co-operation as vehicles for treatment sustainability, this thesis examines the extent to which public health related flexibilities present in the TRIPS Agreement can be used to as enablers of affordable treatment, both in domestic intellectual property legislation, and relevant regional platforms.

The thesis undertakes case studies of the policy and legislative environment in two countries with very different profiles: The United Republic of Tanzania as a least developed country with a nascent local pharmaceutical manufacturing industry and South Africa, as the country with the largest pharmaceutical industry on the continent present the full range of country profiles in the region. Conclusions are drawn regarding the optimization of legislative and policy frameworks to facilitate both the importation and local production of health technologies. Finally, the thesis explores challenges and opportunities facing various south-south co-operation initiatives in the region.

Table of Contents

Statement of Originality	2
Abstract	3
Acknowledgements	7
List of Tables and Figures	8
Acronyms	9
1. Background	13
1.1 Intellectual Property as a determinant of HIV Treatment Sustainability in Eastern and Southern Africa	15
1.2 Aims of Research	22
1.3 Hypotheses	22
1.4 Research Methodology, Sources and Limitations	25
1.4.1 Empirical Data	28
1.4.2 Secondary Sources	31
1.4.3 Analytical Framework	28
1.5 Contribution to the field	31
1.6 Research Outline and Scope	31
2. The Evolution of intellectual Property Law: What Impact on Access to Treatment in Eastern and Southern African Countries?	34
2.1 Intellectual Property and Innovation: What Pathway for Eastern and Southern African Countries?	34
2.2 The Origins of Intellectual Property	38
2.2.1 The First International Intellectual Property Treaties	39
2.2.2 Movement Towards a New International Intellectual Property Agreement	42
2.2.3 The Uruguay Trading Round and the Commencement of Negotiations leading to TRIPS	43
2.3 The TRIPS Agreement Implications on Innovation and Public Health in Developing Countries	46
2.3.1 Public Health Provisions in the TRIPS Agreement: Differences of Interpretation between Countries	49
2.4 The Doha Declaration on TRIPS and Public Health	53
2.5 The 30 August 2003 Agreement and the 2005 Decision to Amend Article 31 of TRIPS	58
2.6 Recent Developments on the enforcement of intellectual property and potential implications on essential medicine access in Eastern and southern Africa	63
2.6.1 Heightened Intellectual Property Protection through Bilateral Trade and Investment Agreements	63
2.6.2 The emergence of ‘TRIPS Plus’ measures through Enforcement and Anti-counterfeiting regulations and legislation	66
2.7 Conclusion	71
3. Using Public Health Related TRIPS Flexibilities to Increase Treatment Access: Experiences from Eastern and Southern Africa	73
3.1 Introduction	73
3.2 Compulsory Licensing and Government use Orders	74
3.2.1 Zimbabwe’s Government Use Order	76
3.2.2 Compulsory licenses in Mozambique and Zambia in 2004	78
3.2.3 An effective compulsory licensing threat in Kenya	81

3.2.4	The WHO-UNICEF “Paragraph 7” Model Letters	83
3.3	Parallel importation	85
3.3.1	The Dispute over Parallel Importation in South Africa	86
3.3.2	Kenya’s interpretation of Parallel Importation	87
3.4	Competition Law as a Public Health Related TRIPS Flexibility	89
3.4.1	Using Competition Law in South Africa to Reduce the Cost of Treatment	91
3.5	The August 30 2003 Agreement	95
3.5.1	Rwanda and Canada’s use of the August 30 2003 Agreement	95
3.6	Conclusion	98
4.	Industrial Property and Related Legislation Relevant to Treatment Access in the United Republic of Tanzania	104
4.1	Tanzania: A Unification of Two Territories	104
4.2	The Public Health Situation in Tanzania and Access to Essential Medicines	106
4.2.1	A Profile of the Pharmaceutical Industry of Tanzania	107
4.2.2	Challenges Facing Local Pharmaceutical Manufacturing: The Role of Industrial Policy and Intellectual Property Related Law	111
4.2.3	Drug Regulatory Authorities in Mainland Tanzania and Zanzibar: a Profile	114
4.3	Tanzania’s Industrial Property and Related Legislation: What Extent Are TRIPS Flexibilities reflected?	117
4.3.1	A Brief Background of Intellectual Property Legislation in Mainland Tanzania	117
4.3.2	Tanzania’s Intellectual Property and Related Legislation: To What Extent are TRIPS Flexibilities Reflected?	121
(a)	Transition periods	121
(b)	Patent Opposition and Revocations	125
(c)	Patentability Criteria and Exclusions from Patentability	128
(d)	Duration of patent, terms, Disclosure, Exhaustion of rights and Exceptions to patent Rights	136
(e)	Exceptions to Patent Rights, Compulsory Licensing and Government Use	138
(f)	Provisions Relating to Intellectual Property Enforcement	142
(g)	Test Data Protection	145
4.4	Conclusion	147
5.	The Incorporation of Public Health Related TRIPS Flexibilities into Patent, Competition and Health Legislation in South Africa: Impact on Access to Health Technologies	151
5.1	Introduction to Legislation and Regulations affecting Access to Health Technologies in South Africa	151
5.1.1	South Africa’s Constitution, Bill of Rights and the Right to Health	152
5.1.2	A brief overview of the South African Regulatory framework	153
5.2	The public health situation in South Africa and Access to Health Technologies	154
5.2.1	A profile of the South African Pharmaceutical manufacturing industry and the Role of Government	157
5.3	South Africa Intellectual property legislation and practices: Their impact on a sustainable supply of treatment	163
5.3.1	Patent Opposition and Revocations	167
5.3.2	Patentability Criteria and Exclusion from Patentability	173
5.3.3	Duration of Patents, Disclosure Requirements, Exhaustion of Rights and General Exceptions	179
5.3.4	Compulsory Licensing and Government Use	183
5.3.5	Provisions Relating to Intellectual Property Enforcement	187
5.3.6	Competition related TRIPS Flexibilities	189
5.4		192

6.	South-South Co-operation: Opportunities and Challenges for Eastern and Southern African Countries within the Region and Beyond	195
6.1	Opportunities for Sub-Regional Co-operation in the East African Community	196
6.1.1	EAC Regional Pharmaceutical Manufacturing Plan of Action	198
6.1.2	The EAC Regional Policy on Intellectual Property and TRIPS Protocol	200
6.2	Opportunities for Sub-Regional Co-operation in the Southern African Development Community	202
6.2.1	The SADC Pharmaceutical Business Plan and Implications Member States	204
6.3	South-South: Cross Cutting Issues Relevant to Both Regions	208
6.3.1	The Pharmaceutical Manufacturing Plan for Africa: Opportunities and Challenges	210
(i)	The African Medicines Regulatory Harmonization Initiative (AMRHI)	214
(ii)	The Pan African Intellectual Property Organisation (PAIPO)	216
6.3.2	The Impact of ARIPO on the Use of TRIPS Flexibilities by its Member States	218
6.3.3	Cross-Regional Co-operation between African Countries and Emerging Economies of the South	222
(i)	Africa's Health partnerships with India, China and Brazil	224
(ii)	IBSA and BRICS configurations: What do They Mean for South Africa on IP and Access to Treatment?	228
6.4	Conclusion	231
7.	Concluding Reflections	235
7.1	Background	235
7.2	Key Findings for Tanzania and South Africa	236
7.3	Prospects for South-South Co-operation on Essential Medicines in Eastern and Southern Africa	240
	Appendix one: Terminology	242
	Appendix two: Recommendations on TRIPS flexibilities in EAC TRIPS policy document	245
	Appendix three: List of people interviewed	247
	Bibliography	248
	Articles and Books	248
	Reports and Policies	266
	Domestic cases	270
	WTO Disputes	272

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List of Tables and Figures

Tables

Table 1: The Use of Public Health Related TRIPS Flexibilities in Eastern and Southern Africa

Table 2: Ten Companies with the Largest Share of the South African Pharmaceutical Market

Table 3: List of Aspen Pharmacare's Voluntary Licenses to Produce ARVs

Table 4: Anticipated need for medicines to treat HIV, TB and Malaria in the EAC

Figures

Figure 1: Number of Medicines Registered by TFDA

Figure 2: New Chemical Entities for Pharmaceutical Use Approved by the US FDA

Figure 3: Nationality of Patent Holders in South Africa in 2008

Figure 4: The Patent Registration Process in South Africa

Figure 5: Distribution of pharmaceutical patents in South Africa 2008 by claim

Figure 6: Map of the East African Community

Figure 7: Member States of SADC

Figure 8: Overlapping memberships of COMESA, EAC and SADC

Figure 9: The Various Stages of Pharmaceutical Manufacturing

Acronyms

AAP	Association of American Publishers
AB	Appellate Body
ACP	African Caribbean and Pacific
ACTA	Anti-Counterfeiting Trade Agreement
AIDS	Acquired Immune Deficiency Syndrome
ALP	Aids Law Project (South Africa)
AMCOST	African Ministerial Conference on Science and Technology
AMRHI	African Medicines Regulatory Harmonization Initiative
ANVISA	Ministry of Health Surveillance Agency (Brazil)
API	Active Pharmaceutical Ingredient
ARIPO	African Regional Intellectual Property Office
ART	Antiretroviral Therapy
ARV	Antiretroviral
AU	African Union
AUC	African Union Commission
AZT	Zidovudine
BI	Boehringer Ingelheim
BMS	Bristol-Myers Squibb
BRELA	Business Registration and Licensing Agency
BRICS	Brazil, Russia, India, China and South Africa
CAC	Competition Appeal Court
CAFTA	Central American Free Trade Agreement
CAMR	Canadian Access to Medicines Regime
CC	Constitutional Court (South Africa)
CBD	Convention on Biological Diversity
CDC	Centre for Disease Control (United States)
CEHURD	Centre for Health, Human Rights and Development
CHAI	Clinton Foundation's HIV/AIDS Initiative
CIPC	Companies and Intellectual Property Commission
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CIPR	Commission of Intellectual Property Rights (United Kingdom)
CIPRO	Companies and Intellectual Property Registration Office
CML	Chronic Myeloid Leukaemia
COMESA	Common Market for Eastern and Southern Africa
COPD	Chronic obstructive pulmonary disease
COSTECH	Tanzanian Commission for Science and Technology
CPTech	Consumer Project for Technology
CVD	Cardio-vascular disease
DFID	Department for International Development
DRA	Drug Regulatory Authority
DRC	Democratic Republic of Congo
DSB	Dispute Settlement Body
DSP	Dispute Settlement Panel
DSU	Dispute Settlement Understanding

EAC	East African Community
EC	European Commission
ECCAS	Economic Community of Central African States
ECOWAS	Economic Community of West African States
EDM	Department of Essential Drugs and Medicines Policy (WHO)
EFTA	European Free Trade Agreement
EPA	Economic Partnership Agreement (European Union)
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAIR	Forum for African Investigative Reporters
FAO	Food and Agricultural Organisation
FDA	Food and Drug Administration (United States)
FIOTEC	Foundation for Scientific and Technological Development in Health
FTA	Free Trade Agreement
FTAA	Free Trade of the Americas
G77	The Group of 77
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GIZ	Gesellschaft für Internationale Zusammenarbeit
GNI	Gross National Income
GPRM	Global Price Reporting Mechanism
GSK	GlaxoSmithKline
GSP	Generalized System of Preferences
GSPOA	Global Strategy and Plan of Action
GTZ	Gesellschaft für Technische Zusammenarbeit
HAART	Highly Active Antiretroviral Therapy
HAI	Health Action International
HDI	Human Development Index
HIV	Human Immunodeficiency Virus
IBSA	India, Brazil and South Africa
ICESCR	International Covenant on Economic Social and Cultural Rights
ICF	Investment Climate Facility
ICT	Information Communication Technology
ICTSD	International Centre for Trade in Sustainable Development
IEPAs	Interim Economic Partnership Agreements
IFC	International Finance Corporation
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IGAD	Intergovernmental Authority on Development
ILO	International Labour Organisation
IMF	international Monetary Fund
INN	International Non-Proprietary Name
INPI	National Institute for Industrial Property (Brazil)
IP	Intellectual Property
IRP	Intellectual Property Rights

ITEC	Indian Technical and Economic Cooperation Programme
ITU	International Telecommunications Union
JPO	Japan Patent Office
KFF	Kaizer Family Foundation
LDC	Least Developed Country
LIC	Low Income Country
LMICs	Low and Middle Income Countries
MCC	Medicines Control Council (South Africa)
MDGs	Millennium Development Goals
MDR	Multiple Drug Resistant (Tuberculosis)
MEA	Ministry of External Affairs (India)
MFN	Most Favoured Nation
MIC	Middle Income Country
MPP	Medicines Patent Pool
MSD	Medical Stores Department (Tanzania)
MSD	Merck, Sharp and Dhome
MSF	Médecins sans Frontières
NAM	Non-Alligned Movement
NAMA	Non Agricultural Market Access
NAFTA	North American Free Trade Agreement
NAPM	National Association of Pharmaceutical Producers
NCDs	Non-Communicable Diseases
NIH	National Institute of Health (United States)
NVP	Nevirapine
OECD	Organisation for Economic Co-operation and Development
OI	Opportunistic Infection
PACRA	Patents and Companies Registration Agency (Zambia)
PACRO	Patents and Companies Registration Office (Zambia)
PAIPO	Pan African Intellectual Property Organisation
PAISA	Pharmaceutical Industry Association for South Africa
PCT	Patent Cooperation Treaty
PEPFAR	President's Emergency Plan for AIDS Relief (United States)
PMA	Pharmaceutical Manufacturers' Association (South Africa)
PMTCT	Prevention of Mother to Child Transmission
QUNO	Quaker United Nations Office
R&D	Research and Development
RIS	Research and Information Systems for Developing Countries
RPMPoA	Regional Pharmaceutical Manufacturing Plan of Action
RTAs	Regional Trading Agreements
SACU	Southern African Customs Union
SADCC	Southern African Development Co-ordination Conference
SADC	Southern African Development Community
SARPAM	Southern African Regional Programme on Access to Medicines and Diagnostics
TAC	Treatment Action Campaign
TACAIDS	Tanzania Commission for AIDS
TB	Tuberculosis

TFDA	Tanzania Food and Drugs Authority
TIDCA	Trade, Investment and Development Cooperation Agreement
TIPASIC	Tanzania Intellectual Property Advisory Service and Information Centre
TPD	Transvaal Provincial Division (South Africa)
TPI	Tanzania Pharmaceutical Industries
TRAC	Centre for Aids Treatment and Research (Rwanda)
TRALAC	Trade Law Centre for Southern Africa
TRIPS	Trade Related Aspects of Intellectual Property Rights
TWN	Third World Network
UDHR	Universal Declaration on Human Rights
UK	United Kingdom
UMIC	Upper Middle Income Country
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development
UNDESA	United Nations Department of Economic and Social Affairs
UNDP	United Nations Development Programme
UNECA	United Nations Economic Commission for Africa
UNESCO	United Nations Economic Social and Cultural Organisation
UNICEF	United Nations Children's Fund
UNIDO	United Nations Industrial Development Organisation
US	United States
USFDA	United States Food and Drug Administration
USPTO	United States Patent and Trademark Office
USAID	United States Agency for International Development
USTR	United States Trade Representative
WCO	World Customs Organisation
WHA	World Health Assembly
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation
XDR	Extensively Drug Resistant (Tuberculosis)
ZAC	Zanzibar AIDS Commission
ZFDB	Zanzibar Food and Drugs Board

1. Background

“The Fight against HIV/AIDS requires leadership from all parts of government- and it needs to go right to the top. AIDS is far more than a health crisis. It is a threat to development itself”

Kofi Annan, United Nations Secretary General

The acquired immune-deficiency syndrome (AIDS) caused by the human immunodeficiency virus (HIV) first captured global community’s attention in the early 1980s when reports emerged of the devastating impact it was having among homosexual males in the United States (US). A few years later, it became clear that the impact of the epidemic would be most acutely felt by the resource constrained countries of sub-Saharan Africa. As of the end of 2012, at least 25 million people had lost their lives to AIDS related illnesses. An estimated 35.3 million people were living with HIV globally as of the end of 2013. Sub-Saharan Africa, a region that is home to an eighth of the world’s population remains the worst affected by the AIDS epidemic, accounting for 71 percent of the global disease burden and three quarters of all AIDS related deaths.¹

Since HIV was identified as the cause of AIDS, there has been large-scale research to discover and develop compounds to treat patients. In 1987, the US Food and Drug Administration (FDA) approved a cancer medicine zidovudine² (AZT) invented in the 1960s as a treatment to stifle the replication of HIV in the human body. Since then, the number of antiretroviral (ARV) agents available has expanded and new treatments, particularly the combination therapies, have had an impressive impact in reducing morbidity and mortality.³ The emergence of combination antiretroviral therapy (ART) to treat HIV, has provided great impetus to the AIDS response. It has

¹ UNAIDS (2013) Global Fact Sheet [Online] Available:

http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/20130923_FactSheet_Global_en.pdf

² Zidovudine was developed in 1964 by the Michigan Cancer Foundation, with significant federal funding. Marketing approval was never obtained for zidovudine as a cancer treatment because of the high levels of toxicity the requisite amounts of zidovudine produced when used for cancer therapy.

³ ARV medicines interfere with the lifecycle of HIV by affecting its ability to replicate in the patient’s body. When administered in dual or triple combination, the therapy becomes even more effective. Once the ability of the virus to replicate has been stunted, the patient’s immune system is able to recover. The recovery prevents the onset of opportunistic infections (OIs) which the body may otherwise have been unable to repel.

also saved millions from a typically painful, undignified death. ART has served as a rallying point for treatment activists who assert that access to ART is a core component of the broader human right to health.⁴ A quarter of a century on from the introduction of the first ARV, patients living with HIV have access to a considerably larger selection of health technologies which can be used to prevent, diagnose and treat the disease.

In addition to the millions of lives saved, the roll out of large scale treatment programmes has had a number of important and beneficial consequences. First, the effective treatment of people living with HIV has had positive outcomes on other diseases such as tuberculosis (TB). ART has been shown to reduce the risk of TB infection among people living with HIV by 65 percent. Second, there is a growing body of evidence to show that patients on ART have a much lower (up to 96 percent reduction) risk of transmitting HIV to their sexual partners. Treatment, as it turns out, is also an extremely effective prevention strategy. Finally, treatment makes economic sense. Recent studies show that large scale HIV treatment programmes have resulted in cost savings across the health-system over the short term. Patients on effective ART spend far less time in hospital requiring treatment for opportunistic infections or end of life care as those people with AIDS do. Aside from cost savings in the healthcare sector, the economic benefits of treatment including increased labour productivity and averted orphan care can offset and exceed the costs of treatment. A definition of the various terms used to refer to treatment access in this thesis can be found in appendix one.

As the effectiveness of medicines used to treat HIV became apparent in the late 1990s, so too did the fact that they were extremely expensive and unaffordable to the vast majority of people in need of treatment. This situation more than any before, drew into sharp focus, the role of intellectual property related legislation and policy as a key factor in the availability and affordability of HIV treatment access. The situation came to a head in the late 1990s and early 2000s as tensions between governments representing the owners of health technologies required to treat HIV and those in greatest need boiled over in a series of national and international disputes. In 2001, the

⁴ The right to health is recognised in several international instruments including in Article 25 of the Universal Declaration of Human Rights (UDHR), Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Other treaties which recognise the right in similar terms including the Constitution of the WHO.

Indian pharmaceutical manufacturing giant Cipla, offered to produce a generic version of a fixed-dose combination ARV at the price of US\$350 per patient per year or effectively a dollar a day, thus making the prospect of affordable treatment a reality. However, the consequences of drug resistance and the development of more efficacious, less toxic, new generation ARVs means that the cost of HIV treatment remains a continuous and present challenge. With the flat-lining of multilateral AIDS funding and a growing expectations that countries in eastern and southern Africa should assume greater responsibility for the maintenance and scale up of treatment programmes, the role of intellectual property policy and legislation in facilitating access to affordable treatment for HIV will become of greater relevance. So too, will the ability of government officials and civil society to effectively use law and policy to scale up and maintain treatment access.

For the purposes of this thesis, it is necessary to clarify some commonly used terminology in the existing literature on intellectual property and access to treatment and other terms used regularly. A list of the aforesaid terminology used in the thesis can be found in appendix one.

1.1 Intellectual Property as a Determinant of Treatment Sustainability in Eastern and Southern Africa

There are several factors that impact on the affordability and availability of ARVs in low and middle income countries (LMICs) in general, including countries in eastern and southern Africa. For the purposes of this thesis, they have been clustered into three sets of issues:

The first set relates to economies of scale and market dynamics. This includes the availability of bilateral and multilateral funding mechanisms like the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM) and the US backed President's Emergency Plan For AIDS Relief (PEPFAR) to finance the procurement of ARVs. They also relate to the capacity of the domestic pharmaceutical manufacturing industry and the availability of competitively priced active pharmaceutical ingredients (APIs) in LMICs with significant manufacturing capacity.

The second set of issues relate to legal, policy and regulatory factors. These include the effectiveness of domestic industrial property, patent, competition and medicines legislation, the industrial policy objectives of LMIC governments and the capacity of drug regulatory authorities to approve new health technologies expeditiously to promote treatment access.

The third set of issues address the ability of the national supply chain to efficiently deliver health technologies across the health system. These include the availability of market intelligence on the pricing and supply of health technologies and the capacity of local authorities to forecast demand for health technologies in order to maintain adequate supplies across national health systems.

While these sets of issues are inter-connected and all have an impact on treatment outcomes, this thesis, in using the TRIPS Agreement as its primary lens, will most closely examine the intellectual property related legislative and policy factors that impede or facilitate treatment access. Moreover, the thesis examines the role that legal, policy and regulatory environments play in facilitating either the importation or local production of health technologies. In so doing, this thesis will touch on some of the factors contained in the first set of issues including economies of scale, market dynamics and local pharmaceutical manufacturing capacity.

Before the entry into force of the TRIPS Agreement in 1995, countries in eastern and southern Africa enjoyed a significant degree of latitude to align their intellectual property, competition and medicines regulations with national development objectives. However, with the adoption of the TRIPS Agreement, eastern and southern African countries who are WTO Members⁵ and not classified as LDCs are now required to recognize patents for inventions in all fields of technology including pharmaceuticals (with limited exceptions) for a minimum period of 20 years and to enforce patent rights. Public health related TRIPS flexibilities remain available and provide countries with some latitude to customize their intellectual property, competition and medicines legislation so as to address their national objectives including the prioritization of public health goals.

⁵ Most countries in the region are WTO Members with the exception of Comoros, Seychelles, South Sudan and Ethiopia who have all commenced the process of acceding to the WTO. The only country in the region yet to start the WTO accession process is Eritrea.

Public health related TRIPS flexibilities can be interpreted and implemented in a manner that promotes public health objectives of WTO Members. A brief synopsis of the key public health related TRIPS flexibilities follows below:

TRIPS Flexibility	Practical Implications
Transitional periods, exclusion from patentability	LDCs are exempt from applying the TRIPS Agreement other than Articles 3, ⁶ 4 ⁷ and 5 ⁸ until 1 July 2021 or a subsequent date determined by WTO Members and can further choose to exempt pharmaceuticals from patentability until 1 January 2016, or a subsequent date as determined by the WTO Members.
Compulsory licenses and government use orders	A compulsory licence authorises a government to license the use of a patented invention to itself or a third party, without the consent of the patent-holder. A compulsory licence authorising the government itself to use a patented invention is also known as a <i>government use</i> license. In the public health context, compulsory licensing can enable domestic production and/or importation of generic medicines by both private and public sectors, and increase access to treatment.
Determining criteria for patentability	While the number of new and innovative pharmaceutical products is small and declining, thousands of patents are being granted for pharmaceuticals. Article 27.1 provides WTO Members the latitude to determine domestic criteria for inventiveness, novelty and industrial applicability, the three step test prescribed by the TRIPS Agreement to reduce instances of ever-greening.
Parallel importation	Pharmaceutical companies often charge lower prices for a medicine in one country than in another, taking into account a range of market

⁶ Requiring WTO Members to give nationals of other Members the same treatment as their own nationals.

⁷ Requiring WTO Members to provide equal trading opportunities to all Members.

⁸ Article 5 notes that “*The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.*”

	factors. Article 6 of the TRIPS Agreement authorises WTO Members to import a patented medicine from the market of another country without the consent of the patent holder.
General exceptions to patentability	Article 30 of the TRIPS Agreement authorises WTO Members to engage in specific of activities without the consent of the patent which would otherwise be regarded as a violation of patent rights. While the language in Article 30 is not specific, two of the most notable exceptions, from the perspective of access to pharmaceutical products, are the early working (or Bolar) exception, and the scientific research or experimental use exception
Protection of test data	Article 39.3 requires WTO Members to protect pharmaceutical test data required to be submitted for marketing approval from unfair commercial use. Article 39.3 only requires protection of undisclosed test data originated from new chemical entities and that which requires considerable effort to generate. Some developed countries have chosen to implement their Article 39.3 obligations by granting a period of exclusive rights on pharmaceutical test data known as data exclusivity. Several developing countries continue to assert their right to define unfair commercial use in the context of their own national interest and laws.
Remedies for anti-competitive behaviour	<p>A number of provisions in the TRIPS Agreement authorise Members to take measures to mitigate anti-competitive behaviour by pharmaceutical companies both in national and international markets. These include:</p> <ul style="list-style-type: none"> • Article 6 which authorises parallel importation, thus providing a remedy to differential pricing in various markets by pharmaceutical companies; • Article 8.2 which authorises Members to take measures to prevent the abuse of intellectual property rights; • Article 31(k) which authorises the use of compulsory licensing to remedy anti-competitive behaviour; and

	<ul style="list-style-type: none"> Article 40, which confers the right on to WTO Members to take action against restrictive licensing practices which may otherwise limit the transfer of technology.
30 August 2003 Mechanism	Under Article 31(f) of the TRIPS Agreement, medicines produced under compulsory license should normally be “predominantly for the supply of the domestic market.” The 2003 WTO Paragraph 6 Decision and the subsequent amendment of Article 31 <i>bis</i> created a temporary waiver from this general rule, to enable the production and export of generic versions of patented medicines under compulsory licence. Under this system, countries with insufficient local pharmaceutical manufacturing capacity may import generic medicines produced under compulsory licence, subject to terms and conditions set out in the Decision. Paragraph 6 of the 30 August Decision also allows WTO Members who belong to regional economic groupings where at least half the members are LDCs to export products manufactured or imported under a compulsory license to other countries within that regional economic grouping.

Yet, despite the presence of policy space, the number of countries that have effectively employed public health related TRIPS flexibilities to facilitate treatment access are relatively few. A 2010 study undertaken by the World Intellectual Property Organisation (WIPO) examining the extent to which five TRIPS flexibilities namely, transition periods, the patentability of substances existing in nature, disclosure-related flexibilities, aspects related to substantive examination and the ex-officio Intellectual Office control of anti-competitive clauses in patent licensing agreements⁹ had been incorporated by 142 countries found that developing countries and LDCs were less likely to have incorporated TRIPS flexibilities than their developed country counterparts. To date, intellectual property legislation in eastern and southern Africa has not been a key determinant of

⁹ See WIPO 2010. *Legislative implementation at the national and regional levels*. CDIP/5/4. Geneva [Online] Available: http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_7/cdip_7_3-main1.pdf

treatment access. The singularly most important intellectual property related development to affect treatment sustainability in eastern and southern Africa since the entry into force of the TRIPS Agreement was the passing of the 2005 Patents Amendment Act in India. The Act which was passed to ensure compliance with the TRIPS Agreement, was a sea-change for a country that previously only provided for patent protection for pharmaceutical processes. The previous Act in India from 1970 had been passed with the explicit aim of supporting the growth of the domestic pharmaceutical industry. The absence of product patent protection in the 1970 Act enabled reverse engineering with the result that Indian companies were able to manufacture and produce generic medicines easily. This led to the country earning a reputation for producing good quality, highly competitively priced medicines, a drastic departure from the pre-1970 era where Indian consumers paid some of the highest prices for medicines in the world. It should be noted that in addition to an enabling legislative environment, India's industrial manufacturing capacity and the availability of highly qualified technical and scientific expertise were critical elements in its scale up of pharmaceutical production.

The role of the Indian generic pharmaceutical manufacturing industry in sustaining national AIDS treatment programmes in eastern and southern Africa cannot be overstated. A study analysing the donor purchases of ARVs in LMICs from 2003 to 2008 across over 100 LMICs including several in eastern and southern Africa found that approximately 80 percent of all ARVs procured in these countries were Indian generics.¹⁰ While India's 2005 Patents Amendment Act has had no impact on the price of first line ARVs because several competitors manufacture first line ART regimens, several of the newer generation ARVs such as raltegravir and etravirine¹¹ are under patent in India and will remain so for years to come. India's Patents Act of 2005 coupled with the limited presence of generic competitors for newer generation ARVs significantly undermines the viability of India as a default producer of easily exportable new generation generic ARVs.

¹⁰ See Waning B, Diedrichsen E, and Moon S (2012) 'A lifeline to treatment: the role of Indian generic manufacturers in supplying antiretroviral medicines to developing countries.' *Journal of the International AIDS Society* 13:35.

¹¹ According to information obtained from the Medicines Patent Pool (MPP) database, a patent was granted in India in 2002 for raltegravir and will be in place until 2022. A patent for etravirine is valid in India until 2019, with additional patent application on a new form awaiting examination, which, if granted, would extend the patent term to 2026.

There is good reason to believe that the intellectual property legislation of eastern and southern African countries and the degree to which they contain implementable, public health related TRIPS flexibilities will play an increasingly important role in sustaining national treatment programmes. National legislation will become a key determinant in sustaining treatment programmes which include newer generation medicines likely to be patented in India and other countries with significant manufacturing capacity. This outlook is supported by three eventualities in the region.

First, the great majority of ART programmes in eastern and southern Africa are funded by multilateral financing mechanisms such as PEPFAR and the Global Fund which in turn, are mostly financed by donor governments. With the onset of the global economic crisis of 2008, multilateral funding for the AIDS response has flat-lined. The year 2011 marked the first time that domestic spending exceeded donor funding of the AIDS response, with the margin widening in 2012. There is a growing realisation by governments in eastern and southern Africa that they will be expected to bear greater responsibility for financing ART programmes in their countries.

Second, with the revision of WHO treatment guidelines in June 2013,¹² the number of people eligible for ART globally increased to an estimated 21.2 million people at the end of 2013, the large majority of who live in Africa. While an impressive scale up in treatment has taken place in recent years, many more people are eligible for treatment than are receiving it at present.

Third, almost all the new generation ARVs are patented in several eastern and southern African countries. Reasons for this include the patent registration system in South Africa, and lax patent examination standards in regional offices which undertake substantive patent examinations on behalf of many countries in the region. Both these points will be elaborated upon below.

¹² WHO (2013) *Consolidated Guidelines on the Use of Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach*, Geneva [Online] Available: http://apps.who.int/iris/bitstream/10665/85321/1/9789241505727_eng.pdf

1.2 Aims of Research

This thesis has three aims. The first is to demonstrate that many countries in eastern and southern Africa have not fully incorporated public health related TRIPS flexibilities into national legislation in a way that would support their ability to sustain and expand national treatment programmes.

The second aim of the thesis is to delve further into the intellectual property related legislative and policy levers available to countries in eastern and southern Africa to sustain and expand national treatment programmes through the use of case studies. The case studies will examine policy options of countries in eastern and southern Africa both with and without significant pharmaceutical manufacturing capacity.

The final aim of this thesis is to demonstrate how the current functioning of regional intellectual property offices such as the African Regional Intellectual Property Organisation (ARIPO) to which most eastern and southern African countries belong, is impeding the sustainability of national treatment programmes. In so doing, the thesis will highlight the importance of policy coherence of recent initiatives aimed at promoting regional co-operation in the trade of essential medicines are to be successful. Recommendations will be made to advance the public health objectives of countries in the region with significant local pharmaceutical manufacturing capacity, and those without.

1.3 Hypotheses

The affordability and availability of health technologies hinges on a number of factors ranging from market dynamics and the legal, policy and regulatory environment, to the capacity of the health system to deliver health technologies across its supply and distribution chain. This thesis will examine the degree to which countries in eastern and southern Africa have incorporated public health related TRIPS flexibilities into national laws with a focus on patent, competition and drug regulatory legislation. In so doing, the thesis will test the following hypotheses:

First, the incorporation of public health related TRIPS flexibilities into domestic legislation has not been a priority for countries in eastern and southern Africa because most patients on ART in the region predominantly are still on first-line ART regimens, which are both affordable, and presently funded by bilateral and multilateral donor institutions such as the GFATM and PEPFAR. The incorporation and use of public health related TRIPS flexibilities has not been needed to treat patients in eastern and southern African countries. However, public health related TRIPS flexibilities will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs increasingly being patented in countries with significant pharmaceutical manufacturing capacity in the region such as South Africa, and elsewhere as is the case in India.

Second, there are capacity constraints within the relevant government departments in eastern and southern Africa that hinder the full integration of public health related TRIPS flexibilities into relevant national legislation and their use when needed.

Third, while capacity constraints and a reliance on donor funding are both present, these two factors alone do not provide a holistic picture of challenges in the region which are more complex than may appear at first glance. There is a significant degree of legislative and policy incoherence at the national and regional levels, which, if not addressed by law reform and increased co-ordination, could undermine the incorporation and use of TRIPS flexibilities both at the national and regional level, thus bringing the sustainability of treatment programmes into question.

As postulated in the second hypothesis, capacity constraints have impeded the full integration and use of public health related TRIPS flexibilities. They have also contributed to the legislative and policy incoherence advanced in the third hypotheses. In some instances however, the underlying reasons for the policy incoherence extend beyond capacity constraints and are the result of overlapping organisational mandates, insufficient co-ordination at the national and regional levels and at times, competing interests between national and regional institutions.

The first two hypotheses largely re-affirm the existing conventional wisdom of much of the academic research in this field, far less research has been undertaken on what impact legislative

and policy coherence at the national and regional levels has had on the ability of countries in eastern and southern Africa to sustain and scale up national treatment programmes. The testing of the third hypothesis would be the primary contribution of this thesis to the rich existing field of literature. The hypotheses advanced are tested by the introduction of three research questions:

- (i) What is the funding source for the national AIDS, TB and malaria treatment programmes and how sustainable is that funding?
- (ii) In the event the current sources of funding are unsustainable, how can public health related flexibilities available in the TRIPS Agreement be employed by countries in eastern and southern Africa to sustain and expand treatment programmes while supporting regional initiatives to strengthen local pharmaceutical industries?
- (iii) What legislative and policy coherence is required to support the more effective use of public health related TRIPS flexibilities by eastern and southern African countries?

The thesis further argues that the considerable differences in levels of industrial development between countries in eastern and southern Africa necessitates a greater distinction being made between countries with significant local pharmaceutical manufacturing capacity and those without. The testing of this argument lies in the country case studies found in this thesis. The country studies will analyse the research questions through the lens of countries with differing capacities in the area of pharmaceutical production. Furthermore, this thesis asserts that any regional initiatives to promote a sustainable supply of essential medicines must be supplemented at the national level with the careful assessment and adaptation of national legislation to incorporate public health related TRIPS flexibilities. This assertion will be tested against the discussion on the various intra-regional and inter-regional initiatives in eastern and southern Africa aimed at fostering co-operation between countries to improve access to essential medicines.

1.4 Research Methodology, Sources and Limitations

The thesis undertakes a comparative analysis of two countries in eastern and Southern Africa, with different profiles, challenges and opportunities, and in so doing, draws conclusions applicable to other countries in the region in similar circumstances. In addition to the two country case studies, a review of exiting regional initiatives aimed at promoting regional co-operation on treatment access in eastern and southern Africa is undertaken. Tanzania and South Africa were identified as the two country case studies for the following reasons. First, both countries have been undertaking intellectual property related policy and legislative reform with implications on treatment access. There has been a significant amount of country level activity and government engagement on the issue. Second, a deliberate decision was taken to conduct studies of two countries with very different profiles. The 24 countries which, for the purposes of this thesis, comprise the eastern and southern African region vary widely with regards levels of industrialisation, income per capita, capacity of government officials and national institutions to effectively implement laws and policies and varying membership of regional economic communities and south-south co-operation initiatives.

In many ways, Tanzania and South Africa represent stark contrasts. Tanzania is ranked 159th out of 187 countries included in the 2014 Human Development Index of the United Nations Development Programme (UNDP). It has a low industrial base, a nascent local pharmaceutical industry and is a net importer of health technologies, a situation unlikely to change in the foreseeable future. Tanzania is classified as an LDC which accords it differential treatment according to WTO rules like many countries in eastern and southern Africa.. Its government officials and institutions are regarded as having increasing but still modest levels of capacity. As with many countries in the eastern and southern African region, Tanzania is largely dependent on multilateral financing to sustain its national treatment programme. The country is a member of both the East African Community (EAC) and Southern African Development Community (SADC), each with different regional initiatives on intra-regional co-operation treatment access.

South Africa on the other hand, is the largest economy on the continent after Nigeria and dominates the SADC region, accounting for 80 percent total trade volumes. It has the largest pharmaceutical

base on the continent and is home to a top 10 global generic manufacturer. The country has comparatively speaking, strong local institutions including a Competition Commission, Medicines Control Council (MCC) and Companies and Intellectual Property Commission (CIPC). It is a member of the BRICS club of countries, a group of five large developing and emerging market economies. South Africa is included as a country case study because it tells a very different story of the region, but also because it is central to many opportunities for regional co-operation on treatment access. Together, these two case studies provide a good assessment of opportunities and challenges facing countries in the eastern and southern African region.

This thesis makes use of both desk reviews of existing literature and empirical data, which often acted as a control mechanism to test the validity of the findings of the desk review

1.4.1 Empirical data

Most of the empirical data were collected during field visits to Tanzania and South Africa. This thesis has benefitted tremendously from my work at UNDP on matters of intellectual property, innovation and trade which entailed providing policy and technical advice to several countries in the eastern and southern African region from 2008 to 2014 as well as the opportunity to interact with government officials working in intellectual property issues in the region.

The data were collected through a limited number of interviews and primarily, though conversations held with key government officials representing the ministries of Trade and Industry, Health and Social Welfare and the ministry of Communication, Science and Technology in Tanzania as well as civil society organisations, representatives of bilateral and multilateral development co-operation organisations and the private sector including local pharmaceutical manufacturers. In South Africa, interviews were conducted and conversations held with officials from the Department of Trade and Industry, Science and Technology, Health and the Competition Commission. Several discussions were also held with members of civil society, intellectual property lawyers, consultants and representatives of the local pharmaceutical manufacturing industry. The interview data in many cases provided an important picture of the intricacies and

political considerations which drove national and regional policy and legislative making in the area of intellectual property.

Field visits to Arusha, Tanzania the headquarters of the East African Community Secretariat took place in March and December 2010. Field visits to Dar es Salaam, Tanzania took place in October 2013 and February 2014. Field visits to South Africa took place in Cape Town in March 2011, Pretoria in June 2011, and Johannesburg in February 2013. All interviews for this study were held on a non-attributable basis because of the political sensitivities involved. Much of the information which was obtained during the interviews is not cited in the thesis if there was a risk of the information being attributable to any given individual. A non-attributable list of interviewees can be found in appendix three.

The cut-off date for data used is October 2014. Attempts to collect information through the use of questionnaires met with limited success. There was a high rate of unresponsiveness of many stakeholders in the region in general and in the research countries. There was also a reluctance on the part of some regional intellectual property officials to share information they considered to be politically sensitive, and to be cited as the source of that information. The interviews and face to face conversations which took place proved to be a valuable source of information and provided much contextual insight. They also served a useful purpose of validating the desk research and acted as a control mechanism to test the validity of the findings.

1.4.2 Secondary Sources

The theoretical data rely on a combination of relevant legal, trade and public health related literature, as well as legislation, protocols and case law. These data are comprised of studies, plans reports from national governments, multilateral organisations including the WTO and a number of United Nations organizations, academic and research institutions, civil society as well as public interest organisations working on issues of intellectual property, trade, competitive and consumer policy, public health innovative financing mechanisms.

1.4.3 Analytical Framework

There is a large volume of existing literature on the use of public health related TRIPS flexibilities to facilitate treatment access in LMICs. Many authors and researchers have noted that the impact of intellectual property legislation varies widely depending to a country's level of development and should be tailored to address specific national objectives including public health. According to the Report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH):

“It is also assumed that society at large will be able to benefit from present and future innovation. But where most consumers of health products are poor, as are the great majority in developing countries, the monopoly costs associated with patents can limit the affordability of patented health-care products required by poor people in the absence of other measures to reduce prices or increase funding. Thus the overall effect of intellectual property regimes is context-specific – the impact in a country such as India may differ from that in Thailand or in Ghana.”¹³

A key question that has emerged since the entry into force of the TRIPS Agreement in 1995 is whether the obligations placed on developing countries who are WTO Members are reasonable and whether the flexibilities present in the TRIPS Agreement provide sufficient latitude to developing country members to address public health concerns. Abbott¹⁴ has argued that the burden of proof to demonstrate the benefits of the TRIPS Agreement to developing countries lies with developed countries and that failure to do so provided sufficient justification for a review of the provisions of TRIPS. Noting that the TRIPS Agreement resulted in billions of dollars in wealth transfer from technology importing countries to technology exporting countries, Dutfield and Suthersanen¹⁵ re-iterate Trebilcock and Howse's assertion that:

¹³ See WHO (2006) Report of the Commission on Intellectual Property Rights, Innovation and Public Health, World Health Organization, Geneva, [Online] Available:

<http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf>

¹⁴ Abbott F, (2001) 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' Occasional paper 7, QUNO, Geneva. In this article written shortly before the fourth WTO Ministerial conference in Doha, he recommended that developing countries request a review of the TRIPS Agreement as it did not sufficiently address their needs.

¹⁵ Dutfield G, and Suthersanen U, (2004) 'Harmonisation or Differentiation in Intellectual Property Protection? The Lessons of history' Occasional Paper 15, QUNO.

*“A country would have little or no interest in protecting intellectual property rights in products of which it is solely an imitator and intends to remain so – here the national interest is above consumer welfare, i.e. sourcing the product as cheaply as possible. Such is the case for many poor countries.”*¹⁶

The debate over the impact of the TRIPS Agreement on developing countries has shifted in recent years away from a possible review and amendment of the TRIPS Agreement to one over whether countries can more effectively utilize public health related TRIPS flexibilities. The reasons for a shift in the debate are several. First, the reality remains that the majority of countries in eastern and southern Africa have not amended their legislation to optimize the use of public health related flexibilities. An effort by developing countries and LDCs to push for an amendment of the TRIPS Agreement stands less chance of success if its proponents are unable to show that they have taken steps to use the Agreement to increase access to treatment and that these efforts have been undermined by the complexities of using public health related TRIPS flexibilities. Deere¹⁷ notes in her book that more than half of WTO developing country Members did not meet the 1 January 2000 deadline to comply with the TRIPS Agreement. Yet, as early as 2007, more than half of the WTO LDC membership had already enacted intellectual property legislation, well in advance of the then 1 July 2013 deadline.

Deere also asserts that the failure of many developing countries and LDCs to change their laws can be linked to the uncertain international legal environment. This is an argument also made by Abbott and Reichman¹⁸ who, in discussing examples of compulsory licensing in Brazil and Thailand ascribe the decision to issue compulsory licenses to the increased public understanding of public health related flexibilities. They contrast the extent of legal certainty that surrounded these licenses in Brazil and Thailand with the situation in South African in 1997, where the

¹⁶ Trebilcock M, and Howse R, (1999) “The Regulation of International Trade” (2nd ed.), London: Routledge, at 314.

¹⁷ Deere C, (2008) “The Implementation Game: The TRIPS Agreement and the Global Politics of Intellectual Property Reform in Developing Countries” Oxford University Press.

¹⁸ Abbott F, and Reichman J, (2007) ‘The Doha Round’s Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions’ Journal of International Economic Law 10(4), 921–987.

incorporation of parallel importation into domestic legislation by the government resulted in a lawsuit by the Pharmaceutical Manufacturers' Association of South Africa.¹⁹

In addition to legal uncertainty, capacity constraints have been identified as another challenge that has impeded the use of public health related TRIPS flexibilities. Musungu and Oh²⁰ found that greater numbers of developing countries and LDCs, possibly buoyed by the Doha Declaration on TRIPS and Public Health, have been incorporating into domestic legislation, and using public health related TRIPS flexibilities in larger numbers since 2001. They identify the eastern and southern African countries of Mozambique, Zambia and Zimbabwe as having issued compulsory licenses or government use orders. While also citing a general lack of clarity about legal options available to countries, Musungu and Oh also identify a lack of local legal and technical expertise to incorporate and implement flexibilities in national law and policy as an obvious problem. Beall and Kuhn²¹ analyse the 24 various occasions between 1995 and 2011 where they assert that a compulsory license was issued, or a scenario tantamount to a compulsory license occurred. They conclude that the barriers to compulsory licensing go well beyond the lack of local pharmaceutical production capacity, and likely extend to health system incapacity, political pressure from developed countries, and the legislative difficulties of issuing compulsory licenses.

In addition to institutional and technical capacity constraints, Matthews,²² identifies pressure from bilateral and regional trade agreements as well as technical assistance provided by both bilateral and multilateral sources as an important determinant in undermining the greater incorporation and use of public health related TRIPS flexibilities by developing countries and LDCs. He notes that many providers of technical capacity focus on intellectual property protection and enforcement rather than the optimization of public health related TRIPS flexibilities and that more should be done to ensure that the technical advice countries receive promotes their national interests.

¹⁹ Pharmaceutical Manufacturers Association of South Africa and Another: In re Ex Parte President of the Republic of South Africa and Others (CCT31/99) [2000] ZACC 1; 2000 (2) SA 674; 2000 (3) BCLR 241.

²⁰ Musungu S, and Oh C, (2006) 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?' South Centre, Geneva.

²¹ Beall R, Kuhn R (2012) 'Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis' PLoS Med 9(1): e1001154. doi:10.1371/journal.pmed.1001154.

²² Matthews D, (2005) 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The problem with Technical Assistance and Free Trade Agreements' EIPR Issue 11, 420-427.

1.5 Contribution to the Field of Research

The brief synopsis of relevant literature referred to above is an indication of the rich debate of relevance to the research problem identified in this thesis. However, little academic research exists which analyses the impact of actual or attempted use of public health related TRIPS flexibilities in eastern and southern African countries and whether the measures adopted by these governments actually resulted in reduced prices or increased availability of essential medicines. In addition, the existing literature in almost all cases identifies capacity constraints, political pressure and inappropriate technical assistance as the primary reasons why more countries have not fully incorporated and used public health TRIPS flexibilities. Far less literature addresses what steps countries should take to address these challenges. Even less literature relates to the role of policy incoherence among the national and regional stakeholders in perpetuating the current situation.

This thesis aims to contribute to the existing literature by examining in detail, how public health related TRIPS flexibilities can be optimally employed by countries in eastern and southern Africa to sustain and accelerate national treatment programmes. In so doing, the thesis will explore in detail, how domestic legislative and policy reform in Tanzania and South Africa can support national policy objectives to sustain antiretroviral treatment programmes. In addition, the thesis will examine how the policy positions and objectives of the different government ministries and stakeholders in South Africa, Tanzania and the regional economic communities may be undermining the progressive policies and initiatives being embarked upon to sustain and accelerate access to treatment for HIV. In so doing, discusses options to address this situation. Finally, the thesis will discuss opportunities to increase the level of policy coherence required to address the inter-connected challenges of treatment access.

1.6 Research Outline

This thesis is structured into seven chapters. Chapter one, which, in addition to providing a snapshot of the current situation with regards the availability of treatment access in eastern and southern Africa, poses the research problem and advances the three hypotheses to be tested in the

subsequent chapters. The first chapter ends with a literature review and an assessment of how this thesis will make a contribution to a rich body of existing literature in this specific field of intellectual property law.

Chapter two focuses on the historical evolution of intellectual property and in so doing, traces the participation of eastern and southern African countries in the multilateral intellectual property rule making process. The chapter further examines the first attempts by developing countries to use the public health related TRIPS flexibilities to advance public health objectives and the differences which arose between developed and developing WTO Members over the interpretation of the TRIPS Agreement. The chapter discusses the impact of the Doha Declaration on the TRIPS Agreement and Public health and the 30 August 2003 Decision. Chapter two concludes with an assessment of some of the emerging developments in intellectual property which may further impede the use of TRIPS flexibilities in the region.

Chapter three examines the degree to which public health related TRIPS flexibilities have been employed by countries in eastern and southern Africa to increase access to treatment and what the outcomes of these attempts have been. The chapter analyses the instances where the use of public health related TRIPS flexibilities did not result in the desired outcome of ARV price reductions and discusses some of the challenges that may have prevented the more effective use of the TRIPS flexibilities.

Chapter four focuses on the first of two country specific case studies of countries in eastern and southern Africa. Tanzania and South Africa have distinct profiles with regards their reliance on multilateral funding to sustain national treatment programmes, the level of sophistication of their local pharmaceutical industries, their membership of different regional economic organisations and their differing rights and obligations under the TRIPS Agreement. Chapter four analyses the case of the United Republic of Tanzania; which comprises mainland Tanzania and Zanzibar, each with its own patent and drug regulatory legislation. As an LDC with a nascent local pharmaceutical industry Tanzania is likely to be a long term importer of health technologies. Chapter four draws conclusions on how the reform of policy and legislation in Tanzania could promote both the importation of health technologies into the country and facilitate their regional trade.

Chapter five examines the case of South Africa, which, as a developing country, was required to have been TRIPS compliant since 1 January 2000. South Africa is home to the most advanced local pharmaceutical manufacturing industry on the continent which in recent years, has been making inroads into the continent with the acquisition of pharmaceutical manufacturing companies in a number of sub-Saharan African countries. In addition, Chapter five examines South Africa's legislative and policy environment in relation to the TRIPS Agreement with a focus on medicines, competition and patent legislation. The role of various government departments in shaping South Africa's policies on treatment access and local pharmaceutical production is examined, as is the policy incoherence which appears to exist between them.

Chapter six examines, from a south-south co-operation perspective, intellectual property policy options available to countries in eastern and southern Africa to increase the trade in health technologies. From the regional perspective, chapter six will focus on the prospects for intra-regional co-operation within the African Union, East African Community and the Southern African Development Community. Chapter six will also explore opportunities for south-south co-operation (as defined in appendix one) between eastern and southern African countries and large developing countries with pharmaceutical manufacturing capacity including India, China and Brazil. Finally, in testing the third hypothesis advanced in this thesis, chapter six will examine how the policy positions and objectives of different regional stakeholders may be undermining the progressive policies and initiatives being embarked upon to sustain and accelerate access to treatment for HIV, TB and other epidemics.

As the conclusion of the thesis, chapter seven will review the hypotheses advanced in chapter one and in assessing their validity, make recommendations on how greater policy coherence can be achieved through legislative and policy reform at the national level, and greater co-ordination among regional economic organisations to promote a sustainable supply of health technologies in eastern and southern African countries.

2. The Evolution of intellectual Property Law: What Impact on Treatment Access in Eastern and Southern African Countries?

“We are simply asking for fair and equitable rules that would take into account our development needs and allow us to participate fully in the trade system. But instead, we risk being pressured again into accepting rules we don’t need and can’t afford...”

Ambassador Nathan Irumba, Mission of Uganda and Representative of Least Developed Countries at the WTO

2.1 Intellectual Property and Innovation: What Pathway for Eastern and Southern African Countries?

The debate over the role of intellectual property in stimulating the innovation of health technologies is a complex one with wide-ranging opinions. Many scholars have argued that high levels of intellectual property protection are necessary to incentivise innovation of new health technologies. According to Grabowski,²³ the costs of pharmaceutical research and development (R&D) are so high and the costs of imitation so low that the originator pharmaceutical industry is more vulnerable to so called ‘free riders’ than other industries. Thus, he argues, patent protection is a key determinant to incentivise the development of new pharmaceutical products.²⁴ He cites the example of Canada, which had incorporated legislation to encourage compulsory licensing and argues that as a result there were very few, if any incentives for originator pharmaceutical companies to undertake R&D. He notes that since the adoption of a legislative environment promoting higher levels of pharmaceutical patent protection, there has been a dramatic growth in R&D investment in Canada’s domestic pharmaceutical industry. Others make the case for stronger

²³ Grabowski H, (2002) ‘Patents, innovation and access to new pharmaceuticals’ Journal of International Economic Law 2002 5(4):849-860, Oxford University Press.

²⁴ He notes that typically, less than 1 percent of the compounds examined in the pre-clinical stage move to clinical trials involving humans and that only 20 percent of the compounds entering clinical trials typically obtain marketing approval from drug regulatory authorities.

intellectual property protection on the basis that it will not only induce greater levels of R&D but that it would also incentivise technology transfer between developed and developing countries.²⁵

Others argue that heightened intellectual property protection, especially in developing countries will provide monopoly power to multinational companies thereby leading to ‘rent extraction’ from poor developing countries.²⁶ Branstetter²⁷ reviews a number of important empirical studies²⁸ and concludes that most fail to find evidence of a strong response in domestic innovation that could be reasonably ascribed to the effects of stronger intellectual property rights. He concludes that, if anything, overly-broad patent rights can actually retard the pace of innovation²⁹ because initial patent holders are able to block the necessary ‘follow on’ research which could have increased quality and lowered the product prices.³⁰ Drahos and Braitwaite note that the property rights which emerge in the market place are not necessarily efficient because those who shape the design of property rights may be less interested in maximizing efficiencies and more interested in exacting rents.³¹ In his book on corporate social responsibility, Banerjee³² argues that while the R&D based pharmaceutical industry routinely cites patent protection as a necessity to guarantee R&D

²⁵ See Evenson R, and Kanwar S, (2001) ‘Does Intellectual Property Protection Spur Technological Change’, Yale Economic Growth Centre Discussion Paper. No. 831. The authors mapped five aspects of patent laws: extent of coverage, observance of international patent agreements, provisions for loss of protection, enforcement mechanisms and the duration of protection in 32 countries from 1981 to 1990. They found that because there is a strong positive association between countries’ intellectual property protection and their R&D investment expenditure that intellectual property rights are significant incentives for innovation.

²⁶ McCalman P, (2001) ‘Reaping what you Sow: An Empirical Analysis of International Patent Harmonization’ *Journal of International Economics* 161-86.

²⁷ Branstetter L, (2004) ‘Do stronger patents induce more local innovation?’ *JIEL* 7(2), Oxford University Press, 359-370.

²⁸ Chief among these is the research by Lerner J, (2002) ‘Patent Protection and Innovation over 150 Years’ National Bureau of Economic Research Working Paper No 8977, Cambridge, Massachusetts. Lerner examined the impact of patent reform across 60 countries over a 150 year period and found that the strengthening of patent laws did not increase domestic patent applications but rather led to significant increases in patenting by foreigners in the reforming country. The two other studies that form the basis of the author’s conclusions are Sakakibara M, and Branstetter L, (2001) ‘Do patents encourage more innovation? Evidence from the 1988 Japanese Patent Reforms’, *32 RAND Journal of Economics* and Branstetter L; and Branstetter L, and Nakamura Y, (2003) ‘Is Japanese Innovative Capacity in Decline?’, in Blomstrom M, Corbett J, Hayashi F, and Kashyap (eds) (1993) “Structural Impediments to Growth in Japan”, University of Chicago Press.

²⁹ *Ibid* Branstetter (2004), at 361.

³⁰ See also Scotchmer S, (1991) ‘Standing on the Shoulders of Giants: Cumulative Research and the Patent Law’ *Journal of Economic Perspectives* 5 at 29.

³¹ Drahos P, and Braithwaite J, (2003) *Information Feudalism: Who Owns the Knowledge Economy?* (New York, New Press, 2003), 19–38

³² Banerjee S, (2007) “Corporate Social Responsibility: the Good, the Bad and the Ugly”, Edward Elgar Publishing, Cheltenham at 56-57.

investment, the reality is that originator pharmaceutical manufacturers spend two to three times more on marketing than on R&D and routinely refuse to divulge their actual R&D costs³³

Other scholars believe that intellectual property policy should be tailored to meet specific contexts and situations. Blair and Cottier for example, distinguish between R&D required for so called public goods such as parks roads, national education and defence and the options available to governments to solve the problem of free riders such as imposing taxes or a user fee on those who uses the resources and the facilities on the one hand and trying to regulate the problem of free riding on other goods such as pharmaceuticals. They argue that for some inventors, there is sufficient incentive to innovate because of the benefit of being the first to bring a product to market, particularly if the costs of reverse engineering the product are high. If, however, the costs of reverse engineering are comparatively low, then the patent system is the most efficient way of addressing the dilemma of free riding.³⁴

The tailoring of intellectual property legislation and policy to meet specific country objectives and priorities is a practice almost as old as intellectual property itself. The principle “one size does not fit all” was the rationale behind the inclusion of public health related flexibilities into the TRIPS Agreement. For the countries of eastern and Southern Africa, the debate over the role of intellectual property in incentivizing pharmaceutical innovation is of particular relevance to South Africa given the manufacturing capacity of its local pharmaceutical sector as elaborated upon in chapter five. Even for South Africa, the question of greater relevance for the purposes of this thesis is how intellectual property legislation and policy can be employed both incentivise domestic innovation while facilitating technology transfer, and affordable access to health technologies in a manner required to sustain national treatment programmes for HIV and other diseases. For other eastern and southern African countries, many of who are LDCs with limited local pharmaceutical

³³ He cites the case of *Bowsher v Merck and Co Inc*, 460 U.S. 824 (1983) in which Merck filed a petition to prevent a US government agency from accessing information on the direct and indirect costs of manufacturing a medicine being supplied to the government agency. The Federal District Court held in a judgement which was upheld by the Court of Appeals, that the agency was entitled to inspect information pertaining to the direct costs including manufacturing and delivery, access to indirect costs which included marketing, promotion, distribution and administration costs did not have to be disclosed.

³⁴ See Blair R, and Cottier T, (2005) “Intellectual Property: Economic and Legal Dimensions of Rights and Remedies” Cambridge University press, at 15.

manufacturing capacity as is the case with Tanzania, intellectual property legislation is more likely to be tailored to sustain national treatment programmes and to incentivise technology transfer to a nascent local pharmaceutical industry.

In unpacking the first two hypotheses advanced in chapter one, namely, that the incorporation of public health related TRIPS flexibilities into national legislation of countries in eastern and southern Africa has not been a priority to date, and that there are capacity constraints within the relevant government departments in the region which explains the partial adoption and integration of public health related flexibilities, this chapter traces the evolution of formal intellectual property rules from the pre-TRIPS era, to the adoption of the TRIPS Agreement and the increased focus on intellectual property protection and enforcement. In so doing, this chapter examines the role of eastern and southern African countries in the negotiations leading to the adoption of the TRIPS Agreement in 1995. The chapter then assesses the reaction of countries in the region when the implications of the TRIPS Agreement on access to medicines became apparent in disputes between developed and developing WTO Members over the interpretation of the TRIPS Agreement in the late 1990s.

Next, this chapter examines the role of countries in eastern and southern Africa in debates at the WTO which led to the adoption of the Doha Declaration on the TRIPS Agreement and Public Health. The chapter then examines how the 30 August 2003 Decision and the potential impact it may have on the ability of countries without significant domestic pharmaceutical manufacturing capacity to sustain national treatment programmes on intellectual property and public health. Finally, the chapter concludes with a discussion of how intellectual property protection and enforcement have evolved within eastern and southern Africa to exceed the minimum standards required by the TRIPS Agreement in some cases, and discusses the potential implications of these developments on access to health technologies.

2.2 The Origins of Intellectual Property

Draho categorises the evolution of intellectual property law into three periods: the territorial, international and global.³⁵ In the territorial phase, patents were essentially only enforceable in the countries where they had been granted. The international phase brought with it the onset of international treaties described below. The global period commenced shortly after world war two, as debates between countries occurred at various UN and multilateral forums, leading eventually to the inclusion of intellectual property into the scope of the Uruguay Round of trade negotiations, and the entry into force of the TRIPS Agreement in 1995. The first recorded intellectual property statute developed with the explicit purpose of promoting innovation dates back to 1474 in Venice.³⁶ Mandich notes that this was the first time a legal and institutional form of intellectual property was developed to establish the ownership of knowledge.³⁷ Interestingly, some important elements present in modern day intellectual property laws can be traced back to the Venetian statute as explained by Mandich below:

*“Venice was the first to have continuously and constantly applied certain rules to patents of invention instead of granting an occasional isolated monopoly. Among these rules were these: the protection always was extended to an inventor, provided that his invention was recognized as useful; that the patent term was limited; that the right was transferrable inter vivos and mortis causa; and that it was subject to a compulsory license in favour of the state, that a patent was forfeited by failure to use it within certain term and that it failed in cases of prior knowledge within the territory of the Republic.”*³⁸

From early on in the evolution process, intellectual property law was used as a policy lever to transfer technology and incentivize innovation. According to MacLeod,³⁹ one of the motivating

³⁵ Draho P, (1997) ‘States and Intellectual Property: The past, the Present and the Future’ in Saunders D, and Sherman B, (eds) *From Berne to Geneva: Recent Developments in International Copyright and Neighbouring Rights*, Australian Key Centre for Cultural and Media Policy, Queensland, Australia, 47-70.

³⁶ May C, (2002) ‘The Venetian Movement: new technologies, legal innovation and the institutional origins of intellectual property’ in Vaver D, (2006) “Intellectual Property Rights: Critical concepts in Law” Volume 3, Routledge.

³⁷ Mandich G, (1948) ‘Venetian patents (1450-1550)’, *Journal of the Patent Office Society* 30: 166-224.

³⁸ *Ibid* Mandich.

³⁹ MacLeod C, (1991) ‘The paradoxes of patenting: Invention and its diffusion in the 18th and 19th century Britain, France and North America’, *Technology and Culture* 32 (4), 885-911.

factors behind the development of the first formal English intellectual property law, the Statute of Monopolies of 1623, which occurred at a time when England was less technologically advanced than both France and the Netherlands, was the goal of incentivizing foreign craftsmen to settle in England in a bid to boost the country's technological base.⁴⁰ From an early point in the development of formal intellectual property laws, countries retained the prerogative to customise their intellectual property laws in order to meet its particular needs or priorities. As Dutfield and Suthersanen⁴¹ observed, by the 1880s, there were five areas of variation between patent systems adopted by countries: the definition of novelty, the length of patent terms,⁴² the treatment of foreign patent applicants, exceptions to patentability and requirements about the local working of a patent. For instance, the German Reichspatentgesetz of 1877 passed six years before the Paris Convention entered into force, excluded from patentability inventions considered to be against public order including several agricultural and chemical products as well as medicines.⁴³ Switzerland suspended its patent system from 1802 until 1888, five years after the Paris Convention came into operation⁴⁴ at which time it was considered a 'patent piracy' country. Even after a patent Act eventually came into force, it excluded substances and processes from patentability until 1978.⁴⁵

2.2.1 The First International Intellectual Property Treaties

The move to expand the domain of intellectual property gained momentum late in the second half of nineteenth century and was to a large degree, driven by influential associations of authors, publishers, lawyers and literary societies interested in the protection of literary and artistic works.⁴⁶

⁴⁰ See Cornish W, (1999) "Intellectual Property: Patents, Copyright, trade Marks and Allied rights" (4th edition), London. While disapproving of monopolies in general, the Statute provided the true and first inventor a 14 year period of exclusivity over the invention. This period of exclusivity was provided on condition that the rights conferred were not in violation of the law, did not generally result in increased prices in the domestic market, did disrupt trade and were not generally inconvenient. The 14 year period of exclusivity could be extended for an additional seven years under certain circumstances.

⁴¹ Dutfield G, and Suthersanen U, (2008) "Global Intellectual Property Law", Edward Elgar Publishing, Cheltenham at 24.

⁴² At the time, the Patent term in the UK was 14 years from date of filing, while France and Germany provided patent protection for 15 years from the date of grant, and the US provided 17 years.

⁴³ Jost D, and Cottier T, (2012) 'Broad Concerns about Nanotechnology Patents: Symptoms and Diagnosis' Working Paper 2012/13, World Trade Institute [Online] Available: http://www.wti.org/fileadmin/user_upload/nccr-trade.ch/wp3/3.3c/NCCR%20WP2012_13_NanoPatentsSymptomsDiagnostic_Jost_Cottier2012June.pdf

⁴⁴ Dessemontet F, (2000) 'Intellectual property in Switzerland', Kluwer Law International at 23.

⁴⁵ Ibid Jost and Cottier at 27 who note that at the time, the founder of Geigy AG, which evolved into the originator Swiss pharmaceutical company Novartis denounced patents as "a paradise for parasites."

⁴⁶ Ibid Dutfield and Suthersanen at 26.

These efforts culminated in the 1883 Paris Convention for the Protection of Industrial Property (Paris Convention) and the 1886 Berne Convention for the Protection of Literary and Artistic Works (Berne Convention), the first binding international intellectual property agreements.⁴⁷ The adoption of these two treaties signalled the beginning of the international phase of Intellectual property law as described above by Drahos. For the first time, the Paris Convention required signatory countries to provide for national treatment of foreign works under domestic laws for patents, trademarks, industrial designs, trade names, appellations of origin and utility models. The World Intellectual Property Organisation (WIPO) to some degree owes its establishment to a perceived need for an organisation to *inter alia*, administer the Paris and Berne Conventions and to promote the harmonization of national intellectual property legislation.⁴⁸

One of the reasons why the Paris Convention was considered acceptable to some developing countries at the time, lay in the policy space countries retained to customise intellectual property legislation to meet national policy objectives with the exception of the national treatment principle.⁴⁹ Under the Paris Convention, countries retained the discretion to determine the duration of a patent's validity under national law, and to exclude certain fields of technology from patentability. The Convention also provided for the revocation of patents, and the issuance of compulsory licenses to remedy abuses by right holders.

An issue of concern for developed countries who were signatory to the Paris Convention was the general reluctance of many newly independent states to sign the Convention as well as a lack of enthusiasm that a number of developing country members had about the misalignment of the Convention's objectives with their own national interests.⁵⁰ South Africa which became a Union in 1910 was the first country in the region to sign the Convention in 1947. Even-though a wave of

⁴⁷ See Matthews D, (2002), "Globalising Intellectual Property Rights – The TRIPS Agreement", Routledge/Warwick Studies in Globalisation, at 11.

⁴⁸ Although created in 1967, the Convention establishing the World Intellectual Property Organisation entered into force in 1970. WIPO officially became a specialized Agency of the UN in December 1974 with the entry into force of the Agreement between the United Nations and the World Intellectual Property Organisation [Online] Available: <http://www.wipo.int/treaties/en/agreement/>

⁴⁹ The national treatment principle required that countries extend to foreigners, the same legal rights and remedies available to their nationals.

⁵⁰ Patel notes that of the original 14 Signatories, Ecuador, El Salvador and Guatemala withdrew from the Convention in 1886, 1887 and 1895 respectively. See Patel S, (1989), 'Intellectual Property Rights in the Uruguay Round: A Disaster for the South?' Economic and Political Weekly, Vol. 24, No. 18, 978-989.

independence swept across eastern and southern Africa resulting in the emergence of at least 20 countries by 1977, less than half of them signed the Paris Convention.⁵¹ Scholars point to a difference of opinion between developed and developing countries over the role of intellectual property as a policy lever for development objectives as a probable reason why so few developing countries including those from eastern and southern Africa agreed to sign the Paris Convention.⁵² Another reason may be advanced for why some countries in the region may have signed the Paris Convention despite the general lack of consensus between developed and developing countries over its purpose and utility. Virtually all the eastern and southern African countries who signed the Paris Convention in the 1970s were newly independent states preoccupied with the political and economic challenges that new nationhood brought with it. Countries in the region also inherited colonial laws which had not yet been customised to reflect national interests. Given the circumstances, intellectual property law reform was unlikely to have been a priority.

A number of developed countries retained their own misgivings about the Paris Convention⁵³ which in their opinion did not contain sufficiently robust enforcement provisions or an effective and binding dispute settlement mechanism. This, combined with a 'pro-development' shift towards intellectual property law reform by large developing countries like Brazil and India fuelled the debate which moved to the UN General Assembly in the 1960s. In 1961, Brazil tabled a draft resolution before the General Assembly calling on the Secretary General to conduct an analysis of the effects of patents on developing countries with the eventual holding of a conference on patents and the special needs of developing countries.⁵⁴ According to Deere, the aim of the Brazilians was to use a subsequent report to push for the revision of the Paris Convention to more appropriately address the needs of developing countries. The international conference never took place.⁵⁵ Meanwhile, 1964 saw the establishment of the United Nations Conference on Trade and Development (UNCTAD), an initiative largely driven by developing countries. In continuing their

⁵¹ These countries in chronological order are: The United Republic of Tanzania in 1963, Madagascar in 1963, Malawi in 1964, Zambia 1965, Kenya and Uganda both on 14 June 1965, Mauritius in 1976 and Burundi in 1977.

⁵² See de Koning M, (1997), 'Why the Coercion-based Approach is not the only answer to international piracy in the Asia-Pacific Region' *European Intellectual Property Review* 2: 59-77.

⁵³ Ibid Patel. See also Scotchmer S, (2001) 'The Political Economy of Intellectual Property Treaties' Institute of Economic and Business Research, Working Paper E01-304, University of California, Berkley at 5-6. [Online] Available: <http://www.wcfia.harvard.edu/sites/default/files/Scotchmer2001.pdf>

⁵⁴ Deere C, (2009) 'Developing Country Perspectives on Intellectual Property in the WTO: Setting the Pre-TRIPS Context' *Research Handbook on Intellectual Property Law and the WTO*, Edward Elgar, Oxford.

⁵⁵ Ibid Deere at 8

efforts to push for the revision of the Paris Convention, developing countries in 1970, tabled a Resolution in the UN General Assembly on an ‘International Development Strategy for the Second UN Development Decade calling for, among other things, a review of the international Convention relating to patents.’⁵⁶

2.2.2 Movement Towards a New International Intellectual Property Agreement

Developed countries on the other hand also intensified their efforts to revise both the Paris and Berne Conventions, which led to the establishment of WIPO in 1967. This momentum was bolstered by various industry associations who focused on the impact of piracy and the increase in copyright violations which they alleged, was leading to a decline in revenue.⁵⁷ The attempted consolidation of the Paris and Berne Conventions met with a tepid response by developing countries following the release of a 1974 report by UNCTAD⁵⁸ which found that 84 percent of patents published in developing countries were owned by the nationals of five countries - the US, France, Germany, Switzerland and the United Kingdom (UK) - and that less than one percent of patents in developing countries were filed by nationals. After a number of unsuccessful attempts in 1980, 1981, 1982 and 1984 to revise the Paris Convention, it became clear to developed countries that another avenue to increasing the scope of international intellectual property protection would have to be found.⁵⁹

⁵⁶ See Resolution 2626, adopted during the 25th Session of the UN General Assembly dated 24 October 1970.

According to paragraph 64:

“Developed and developing countries and competent international organizations will draw up and implement a programme for promoting the transfer of technology to developing countries which, will include, inter alia, the review of international conventions on patents, the identification and reduction of obstacles to the transfer of technology to developing countries, facilitating access to patented and non-patented technologies to developing countries under fair terms and conditions...”

See also Baker B, and Avafia T, (2011) ‘*The Evolution of IPRs: From Humble Beginnings to the Modern Day TRIPS Plus Era: Implications for Treatment Access*’ Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7-9 July 2011.

⁵⁷ See Blakeney M, (1995) ‘Intellectual Property in World Trade’, *International Trade Law and Regulation*, 1, 76-81.

⁵⁸ UNCTAD (1974), ‘The Role of the Patent System in the Transfer of Technology to Developing Countries’, New York, UN Publications.

⁵⁹ For a summary of the 1974 UNCTAD report, the differences in position between the developed and developing countries as well as comprehensive discussion on the unsuccessful attempts by developed countries to revise the Paris Convention to contain more comprehensive enforcement and dispute settlement provisions until the commencement of the Uruguay Trade round in 1986, refer to Matthews 2002, at 11-17.

Meanwhile, during the 1970s, industry associations intensified their efforts to make a stronger case for intellectual property protection. These initiatives were led by the Association of American Publishers⁶⁰ (AAP), the Anti-counterfeiting Coalition, the Intellectual Property Committee, an international business coalition whose membership included originator pharmaceutical manufacturers and the Copyright Alliance.⁶¹ The failure to successfully introduce more stringent law enforcement and binding dispute settlement provisions into the Paris Convention and a stalling of the Tokyo Round of the GATT negotiations⁶² prompted the US government to move away from its case by case approach to intellectual property infringements and to introduce amendments to Section 301 of the Trade Act of 1974.⁶³ The revised Section 301 enabled the US to place pressure on countries to meet its demands for intellectual property protection, and in effect, for a clearer nexus between intellectual property protection and trading rules to be drawn.⁶⁴

2.2.3 The Uruguay Trading Round and the Commencement of Negotiations Leading to TRIPS

As the Uruguay round of trade negotiations commenced in 1986,⁶⁵ it was clear from the outset that there was a divergence of opinion over the inclusion of intellectual property between the developed countries, in particular, the US, and developing countries operating (in this instance) under the group of 10 (G10)⁶⁶ umbrella whose membership included Egypt, Nigeria and Tanzania. The US proposed that intellectual property be added to the negotiations because of the GATT's binding dispute settlement mechanism.⁶⁷ The G10 questioned whether the GATT was the most appropriate

⁶⁰ The AAP is the principal trade association of U.S. book publishing industry.

⁶¹ See Sell S, (1998), 'Power and Ideas: The North-South politics of intellectual property and anti-trust', State University of New York.

⁶² The Tokyo Trade Round of the GATT took place from 1973 to 1979, involved, at its height, negotiations between 102 countries and is remembered for being the first round where non-tariff barriers were the subject of negotiation between GATT Contracting States.

⁶³ Section 301 of the Trade Act of 1974 is the statutory provision which gives the US government authority to impose trade sanctions against foreign countries maintaining policies, laws or practices which violate or impinge on US rights under existing trade agreements.

⁶⁴ Henderson E, (1997) 'TRIPS and the Third World: The Example of Pharmaceutical Patents in India', European Intellectual Property Review 11, 651-663, at 652.

⁶⁵ The Uruguay Trade Round of negotiations, the most ambitious of the GATT trade rounds took place from 1986 to 1994 and extended the scope of negotiations beyond goods to the new areas of services and intellectual property.

⁶⁶ The G10 countries opposed to the inclusion of intellectual property into the negotiations were Argentina, Brazil, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania and Yugoslavia.

⁶⁷ Stewart T, (1993) "The GATT Uruguay Round: A negotiating history (1986-1992)", Netherlands, Kluwer Law and Taxation Publishers.

forum to address intellectual property matters, arguing instead that WIPO was the most appropriate organisation.⁶⁸

Early on in the negotiations, the US sought to expand the subject matter being negotiated to include patents, trade secrets, industrial designs, integrated circuit designs, copyright and trademarks with each GATT contracting party to implement the requisite national laws to protect these various aspects of intellectual property.⁶⁹ This led again to a polarisation between developed and developing countries over whether the scope of the intellectual property subject matter being negotiated.⁷⁰ The impasse was essentially resolved following the threat of bilateral trade sanctions by the US under Section 301 of the Omnibus Trade and Tariff Act of 1988.

In April 1991, the USTR placed India, China and Thailand on its priority watch list for inadequate patent protection of pharmaceutical products and the piracy of books, tapes and videos under copyright protection in the US.⁷¹ In 1992, the US revoked tariff concessions that India had for pharmaceutical products, resulting in an estimated US\$ 60 million loss. Shortly thereafter, the Republic of Korea and Brazil were threatened with bilateral trading sanctions on the basis of their alleged violations under Section 301. These incidents, together with ‘negotiation fatigue,’ (the Uruguay round had commenced in 1986) a shortage of qualified technical experts representing most developing countries at the GATT Secretariat in Geneva and a strategy of threatening those countries perceived to be paying inadequate attention to intellectual property protection while offering much sought after concessions to key developing countries in the areas of agriculture and textiles,⁷² meant that by the final stages of the Uruguay Round negotiations in the first few years of the 1990s, the majority of developing countries had stopped opposing the inclusion of the TRIPS

⁶⁸ Ibid Blakeney 1996 at 544.

⁶⁹ Ibid Stewart at 2266.

⁷¹ Ibid Stewart at 2259

⁷² Ryan M, (1998) ‘Knowledge Diplomacy: Global Competition and the Politics of International law’ 9: 11-67. Also refer to Michalopoulos C, (2002) ‘Special and Differential Treatment of Developing Countries in TRIPS’ Quaker United Nations Office (QUNO) at 11 [Online] Available: <http://www.quno.org/geneva/pdf/economic/Issues/Special-Differential-Treatment-in-TRIPS-English.pdf>

The author suggests that if a bargain was done on the inclusion of TRIPS, it would have been facilitated by developed country commitments to liberalise trade in agriculture and textiles. The irony is that these were two sectors in which developed country practices were already in violation of the GATT (in agriculture, because of the sector was previously excluded from trade liberalisation within the GATT and in textiles, where developed countries insisted on maintaining import quotas, in clear violation of GATT provisions.

Agreement under the umbrella of the soon to be established WTO. The TRIPS Agreement was duly adopted as one of the key Agreements of the newly established WTO.⁷³

A combination of reasons have been provided by various scholars as to why eastern and southern African countries were not more actively involved in the intellectual property related aspects of the Uruguay round of negotiations. Matthews has suggested that developing countries were not completely aware of the far-reaching implications of the negotiations and were hampered by a lack of resources and adequate information to meaningfully participate.⁷⁴ Adede⁷⁵ offers two reasons why eastern and southern African countries did not object more actively to the inclusion of intellectual property under the ambit of the WTO. First, he argues that even though developing countries including the African Group did not believe that increased intellectual property protection would be in their developmental interests, when presented with market access which would result in gains in agriculture, textiles and tropical products, the Uruguay round seemed more attractive to them. Second, once the Section 301 Watch list was deployed by the US against large developing countries, African countries may have believed that it was more strategic to engage in multilateral negotiations than to make bilateral concessions and that a multilateral framework with a dispute settlement mechanism in place, would ultimately be more in their interests, than unilateral sanctions imposed by large, influential countries like the US. Regardless of what the reasons may have been, a review of proposals by a group of 12 developing countries included Egypt, Nigeria Tanzania, and subsequently, Zimbabwe in 1990 would suggest that countries had made the decision to negotiate on the contents of an inevitable multilateral agreement on intellectual property rather than to opposing its inclusion.⁷⁶

⁷³ The TRIPS Agreement was adopted during the conclusion of the Uruguay Trade Round in Marrakesh, Morocco on 12-15 April 1994.

⁷⁴ See Matthews D, (2002) 'Trade Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?' CGSR working paper no 99/02, University of Warwick, at 3[Online] Available: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=319545

See also Arewa O, (2006) 'TRIPS and Traditional Knowledge: Local Communities, Local Knowledge and Global Intellectual Property Frameworks' Marquette Intellectual Property Review, Vol. 10, 156, Northwestern University [Online] Available: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=889384

⁷⁵ Adede A, (2001) 'The Political Economy of the TRIPS Agreement: Origins and History of Negotiations' presented as a background paper at a stakeholders' dialogue for eastern and southern African countries in June 2001 [Online] Available: <http://www.ppl.nl/bibliographies/wto/files/1273.pdf>

⁷⁶ See MTN/GNG/NG 11/W71.

2.3 The TRIPS Agreement and Implications on Innovation and Public Health in Developing Countries: Benefit or Burden

When the Uruguay round of trade negotiations commenced in 1986, more than 40 GATT Members did not provide patent protection for pharmaceutical products.⁷⁷ As it entered into force in 1995, the TRIPS Agreement prescribed minimum standards of intellectual property protection and enforcement on WTO Members. These minimum standards apply to the availability, scope and use of intellectual property rights (IPRs) in copyrights and related rights, trademarks, geographical indications, industrial designs, patents, layout-designs (topographies) of integrated circuits and protection of undisclosed information.⁷⁸ Developing countries and LDCs who were WTO Members saw a large reduction of policy space that could be used to customise national intellectual property policy regimes to meet their specific industrial and strategic objectives. While some policy space remains, the TRIPS Agreement constitutes a definitive expansion on the minimum standards required by the Paris Convention. Much has been written about the policy space available to developing countries to enact patent laws aimed at promoting local innovation and technology transfer.⁷⁹ From the perspective of countries in eastern and southern Africa, if the bulk of innovation remains concentrated in developed countries where there is a high probability of strong patent protection, there is precious little incentive to strengthen intellectual property laws which may act as a further impediment to the diffusion of that technology.⁸⁰

⁷⁷ WHO, (2002) Network for monitoring the impact of globalisation and TRIPS on access to medicines, Health Economics and Drugs, EDM Series no 11, WHO/EDM/PAR/2002, 1.

⁷⁸ Falvey E, (2002) 'Trade and the Globalisation of Patent Rights', Internationalisation of Economic Policy, University of Nottingham at 22.

⁷⁹ Correa C, (2000) "Intellectual Property Rights and the use of compulsory licenses: Options for developing Countries" South centre T.R.A.D.E. Working papers, 5, Geneva: South Centre. One of the conclusive findings of the UK established Commission on Intellectual Property Rights (CIPR) was that a one size fits all approach is not a desirable goal. At certain stages of a country's development, weak levels of intellectual property protection are more likely to yield results than strong intellectual property protection. The Commission also drew the distinction between developing countries (e.g. India on the one hand and Swaziland on the other) and concluded that the different levels of scientific and technological capacities should determine what their optimal IPR system should be and that the IP regime most suitable in developing countries could vary widely.

⁸⁰ Ibid Flavey at 19. A World Bank Publication, World Bank, (2001), 'Global Economic Prospects and the Developing Countries' Washington DC, World Bank found that TRIPS represents a yearly US\$ 20 billion transfer of wealth from the technology importing nations, most of who are developing countries, to the technology exporters, most of who are developed countries.

The other notable impact of the TRIPS Agreement for developing countries relates to the costs of administering a patent system. A fully functioning patent office should have the means to scrutinise the validity of patent applications and to adjudicate in the event of a dispute over the registration, maintenance and enforcement of a patent.⁸¹ In 2002, the World Bank estimated that the administrative costs of complying with TRIPS. In Egypt, it was estimated that fixed costs would amount to approximately US\$ 800 000 with annual training costs of US\$ 1 million. Bangladesh estimated a start-up (including the drafting of legislation) cost of at least US\$ 250 000 and an annual cost of more than US\$ 1.1 million for judicial work, training and efforts to increase enforcement.⁸² An UNCTAD study conducted shortly after the TRIPS Agreement came into force estimated that the costs of establishing a functioning intellectual property protection and enforcement system are in the range of US\$ 1.5- US\$ 2.0 million while the operating costs are estimated to be in the region of US\$ 1 million per annum.⁸³

The pecuniary costs are the tip of the iceberg when considering the costs involved in strategically leveraging a national intellectual property system. There are other expenses related to the meaningful participation in norm setting, which includes maintaining country representation in forums where intellectual property is debated and negotiated. According to a study paper presented before the 2002 UK CIPR:

“For any country, effective participation in these organisations requires, we argue, a combination of four main elements of institutional capacity: permanent representation in Geneva; appropriately staffed expert delegations able to attend WTO/WIPO meetings; adequate technical support for policy analysis within the lead government departments; and functional mechanisms

⁸¹ According to advice provided by WIPO to LDCs in a document entitled “*Establishing and Modernizing the Structure and Administration of an Intellectual Property Office, Services and Facilities*”, LDCs are encouraged to establish an Intellectual Property Office, which would, inter alia, examine patent applications and oppositions, publishing applications, grants and refusals, promoting the use of the patent system and disseminating information to the general public. The document also recommends that the Industrial Property Office be divided into departments including: (a) The Directorate General, (b) a Patent Department, (c) a Trademark Department, (d) An industrial designs department (e) Other Registration Departments and Devices; and (f) other Titles of Protection or Subject Matters. This paper while written in 2001, did not elaborate on the fact that LDCs did not have to implement the TRIPS Agreement except Articles 3, 4 and 5 until 1 January 2006 at the time, which has been extended subsequently to 1 July 2021 or a subsequent date as agreed by WTO Members.

⁸² See World Bank (2002) ‘Global Economic Prospects and the Developing Countries: Making Trade Work for the Poor, Washington DC for a discussion of some of the administrative costs facing developing countries.

⁸³ UNCTAD (1996) ‘The TRIPS Agreement and the Developing Countries’, UNCTAD, Geneva.

for policy co-ordination and discussion “in capital”. Effective permanent representation in Geneva is important for ensuring good information flows back to capital; participation in informal consultations (like the WTO Green Room meetings) as part of the negotiating process; alliance building with like-minded countries; eligibility for Chairmanship of WTO meetings; and for better access to the invaluable services and assistance available from the WTO and WIPO Secretariats. The limitations and constraints to effective participation that derive from lack of permanent representation in Geneva... continue to apply for a significant number of developing countries”⁸⁴

The authors found that in 2002, at least 20 of the 45 LDCs that were Members of the WTO or WIPO Member States did not have official representation in Geneva.⁸⁵ Even those who had representation were severely resource constrained and had inadequate representation in Geneva with one or two professionals who struggled to cope with the overwhelming volume of meetings in Geneva, many of them taking place simultaneously.⁸⁶ According to Schaffer:

“Because of capacity constraints, many developing countries are unable to advance their interests in WTO negotiations, before WTO committees, and in dispute settlement as effectively as their developed country counterparts.”⁸⁷

Aside from the lack of negotiating capacity and access to information which impeded more active participation of developing countries, Watal has suggested that lack of access to reliable economic impact assessment on the impact of the TRIPS Agreement played a role in shaping the response of developing countries to the TRIPS Agreement.⁸⁸ As the full implications of the TRIPS Agreement on access to HIV treatment became clearer, developing countries began to assert that developed countries were not meeting their commitments, under Article 66.2 by failing to provide

⁸⁴ Leesti M, and Pengelly T, (2002) Study Paper 9, “Institutional Issues for Developing Countries in Intellectual Property Policy Making, Administration & Enforcement” UK Commission on Intellectual Property Rights, [Online] available: http://www.iprcommission.org/papers/pdfs/study_papers/sp9_pengelly_study.pdf

⁸⁵ Ibid Leesti and Pengelly at 24.

⁸⁶ Sampson G, (2000) ‘Trade, Environment and the WTO: the Post Seattle Agenda’. As Sampson, the former Director of the WTO’s Trade and Environment Division, notes, the Egyptian delegation to the WTO has estimated that there were 2,847 meetings in the WTO in 1997, or an average of 10 meetings per working day.

⁸⁷ Schaffer G, (2006) ‘Can WTO Technical Assistance and Capacity Building Serve Developing Countries’, Wisconsin International Law Journal, [Online] available: <http://hosted.law.wisc.edu/wilj/issues/23/4/shaffer.pdf>

⁸⁸ Ibid Watal 1999.

adequate incentives to facilitate the transfer of technology.⁸⁹ A number of developing countries began calling for a review of the TRIPS Agreement in the late 1990s.⁹⁰ Interestingly, calls for the review of TRIPS were based on a lack of consensus on negotiations around geographical indications and later expanded to include concerns that developing countries including Kenya had regarding provisions in the TRIPS Agreement affecting the sovereignty that countries have over natural resources as reflected in the United Nations Convention on Biological Diversity (CBD).⁹¹ There were, also to be sharp differences of opinion between developing and developed countries over the interpretation of the TRIPS Agreement as discussed below.

2.3.1 Public Health Provisions in the TRIPS Agreement: Differences of Interpretation between Countries

The lack of consensus between WTO Members over the use of public health related TRIPS flexibilities became apparent shortly after the establishment of the WTO. After 1995, developing countries soon began to re-assess the Agreement with the intention of identifying the ambiguities that existed as well as any manoeuvring room which remained for domestic intellectual property policy making.⁹² India interpreted to Article 70 of the TRIPS Agreement in a manner which brought it into dispute with the US, resulting in the first use of the WTO Dispute Settlement Mechanism⁹³ to resolve an intellectual property dispute. The dispute originated from the claim by the US that India had not complied with its obligations under Article 70.8 which, *inter alia*, included a requirement to implement a mailbox mechanism to receive and preserve applications pending the availability of patent protection for pharmaceutical and agricultural chemical products⁹⁴ and that India had failed to establish a legal mechanism for the granting of exclusive

⁸⁹ See Matthews 2002 at 28.

⁹⁰ Ibid Matthews 2002 at 34.

⁹¹ WT/GC/W/302.

⁹² Reichman J, (1998) 'Securing Compliance with the TRIPS Agreement after US v India', JIEL, Oxford University Press 585-601 [Online] Available:

http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=2226&context=faculty_scholarship

⁹³ See the first Dispute Settlement Panel (DSP) Report *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products* WT/DS50/R, 5 September 1997 and the Appellate Body (AB) Report *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products (India- Mailbox)* WT/DS50/AB/R. 19 December 1997.

⁹⁴ Article 70.8 required countries like India that were making use of transitional arrangements to establish a means by which applications for patents could be filed, to apply the same criteria of patentability as contained in Article 27.1 and to provide patent protection for the 20 year minimum period prescribed under Article 33, from the date of filing of the patent.

marketing rights. On the issue of exclusive marketing rights, according to India's interpretation of Article 70.9, it was not obliged to create the legal mechanism for exclusive marketing rights until such need arose. Both the Panel and the Appellate Body found that India had not met its obligations under Articles 70.8 and 70.9 with the AB finding that India's textual obligation under TRIPS was to provide a means to implement its mailbox obligations and the establishment of a mechanism to grant exclusive marketing rights.⁹⁵

This decision together with a potentially unclear understanding of an LDC's minimum obligations under the TRIPS Agreement reportedly led to Ugandan officials debating whether to include a mailbox in a draft patent Act in September 2009 ⁹⁶ despite LDCs not having to comply with the provisions of the TRIPS Agreement except articles 3, 4, and 5 until 1 July 2013, at the time, an exemption which has been further extended to 1 July 2021.

The next public health related intellectual property dispute involved the US and Brazil and related to the local working provisions in Brazil's Industrial Property Law.⁹⁷ Article 68 of the Brazilian Industrial Property Law authorises the government to issue compulsory licenses when manufactured goods are not being produced locally three years or more after a patent has been granted by the authorities. The US took issue with Article 68 on the grounds that it was overly broad in its scope and that Brazil could have issued a compulsory license under Article 71 on the grounds of national health emergency.⁹⁸

⁹⁵ Ortino F, and Petersmann E, (2004) "The WTO Dispute Settlement system: 1995-2003" Kluwer Law International, 422.

⁹⁶ Discussion with Sisule Musungu, 17 February 2010. Subsequently, the Ugandan Parliament passed an Industrial Property Act in 2013. The Act came into force in January 2014 upon assent by the President does not contain a provision for a mailbox.

⁹⁷ Amendments to Brazil's patent law were enacted in 1996 and came into force on 1 January 1997.

⁹⁸ See ICTSD Report of 8 May 2001 entitled '*US-Brazil War of words over pharmaceuticals and intellectual property*' [Online] available: <http://ictsd.org/i/ip/39980/>. For more on the US position, refer to the USTR, 2001, 'Special 301 Report', Washington DC: United States Trade Representative [Online] Available: http://hongkong.usconsulate.gov/uploads/images/3eyF5a1qp15PmBar9Y4QgA/usinfo_301_special2001.pdf

Although the US requested consultations⁹⁹ and the establishment of a panel¹⁰⁰ with Brazil under the WTO Dispute Settlement Understanding, (DSU) on 30 May 2000, the matter was resolved through a “settlement agreement” between the parties, resulting in the US withdrawing its complaint. Shadlen¹⁰¹ believes that intense pressure from AIDS activists both domestically and internationally (who believed that the US complaint was an attack on Brazil’s national public health care programme which provided free ARVs to anyone in need) played a role in the matter being resolved between the parties. He also asserts that there was also a fear on the part of the US that a DSP might find against the US, thereby creating an undesirable precedent. It was therefore in the interests of both parties to resolve the dispute without the risk of a precedent going against them. Considerable pressure was also placed on the US through the tabling of a resolution at the United Nations Human Rights Commission which called for the availability of appropriate medicines for the treatment of AIDS to be made available at accessible prices and which reminded UN Member States that access to ART was a fundamental human rights issue.¹⁰² The resolution was adopted by every member of the Commission except the US, which led to its further isolation on the issue.¹⁰³

The next dispute between developed and developing countries over the interpretation of the TRIPS Agreement captured the attention not only of governments in eastern and southern Africa, of but that of the media, patient groups and civil society activists worldwide. The reasons for this are linked to the fact that an African country was involved in the dispute, and because South Africa had become the global epicentre of AIDS epidemic.

While the first antiretroviral medicines had begun to emerge in the mid-1990s, their prohibitive cost, in excess of US\$ 12 000 per patient per year, combined with the large number of people in

⁹⁹ Request for Consultations by the United States, *Brazil – Measures Affecting Patent Protection*, WT/DS199/1, G/L/385, IP/D/23, 8 June 2000.

¹⁰⁰ Request for the Establishment of a Panel by the United States, *Brazil- Measures affecting Patent Protection* WT/DS199/39, January 2001.

¹⁰¹ See Shadlen K, (2007) ‘The political economy of AIDS treatment: intellectual property and the transformation of generic supply’ *International Studies Quarterly*, 51: 559–581

¹⁰² Commission on Human Rights resolution 2001/33, Access to medication in the context of pandemics such as HIV/AIDS, UN Doc. E/CN.4/RES/2001/33, 20 April 2001.

¹⁰³ For more on the various strategies employed by the Brazilian government in its dispute with the US, see Bird R, and Cahoy D, (2008) ‘The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach’, *American Business Law Journal*, Volume 45, Issue 2.

need of treatment made a national sponsored treatment programme un-feasible. In a bid to make use of the limited policy space the TRIPS Agreement still afforded it, on 30 October 1997, the South African Parliament passed the Medicines Control and Related Substances Amendment Act.¹⁰⁴ The Act contained provisions including Section 15 (C), which appeared to allow a Minister of State,¹⁰⁵ broad discretionary powers to authorise parallel importation as a means of reducing essential medicine prices.¹⁰⁶ The South African chapter of the Pharmaceutical Manufacturers' Association (PMA) launched a High Court application to suspend the Act from coming into operation because of what it perceived to be the presence of unfair wide-ranging powers which could be improperly used. One of the contentions was that, in addition to parallel importation, Section 15(C) could be utilised for compulsory licensing and that, in its present form, it was contrary to Articles 6, 27, 28 and Article 31 of the TRIPS Agreement. Interestingly, the US government opted not to bring the matter before the WTO Dispute Settlement Mechanism. Two reasons are offered for this. The first relates to the strong emotions the case evoked and the potential public relations disaster which eventually led to the application being dropped by the PMA and a settlement being reached in April 2001.¹⁰⁷ The second may explain the settlement the US reached with the Brazilian government in an earlier dispute. A DSP precedent in favour of the South African government might have prompted other countries to adopt similarly wide-ranging provisions.¹⁰⁸

Although the disputes between Brazil and South Africa were resolved without either country having to amend or renounce legislation, developing countries remained concerned that attempts to utilise intellectual property legislation to alleviate public health crises were being met with stiff resistance. Meanwhile, a combination of factors including the court case brought against the South

¹⁰⁴ Act 90 of 1997.

¹⁰⁵ It can be argued that the phrase '*a minister of state*' as opposed to '*the minister of state*' enables the Minister of Trade and Industry, Health or indeed, any government minister to use Section 15(c).

¹⁰⁶ See Watal (1999).

¹⁰⁷ See Tickell S, (2001) 'Cutting the Cost of Drugs', Managing Intellectual Property, March 3. No case since has had a greater impact on the reputation of the originator pharmaceutical industry. See also Baker and Avafia.

¹⁰⁸ Abbott F, (2002), 'The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO, 5 (2), Journal of International Economic Law 469 at 486, has suggested that the reason for the US government withdrawing its support for the pharmaceutical companies was to some degree, related to the NGO protesters threatening to disrupt the presidential campaign of then Vice President Al Gore unless the US withdrew its support to the pharmaceutical industry on this and similar public health disputes.

African government,¹⁰⁹ the rapidly growing HIV epidemic in sub-Saharan Africa, a realization that the US was prepared to use the WTO Dispute Settlement Mechanism to enforce intellectual property rights as well as continued unilateral pressure imposed by the US by placing countries on watch-lists through Section 301 propelled the African Group at the WTO¹¹⁰ to more actively begin seeking clarification on the use of TRIPS flexibilities to increase access to more affordable health technologies.¹¹¹ These initiatives include the adoption of a resolution by the 57th Session of the United Nations Human rights Commission calling, *inter alia*, on UN Member States to refrain from taking measures which would impede access to medicines and encouraging countries to adopt legislation and regulations to facilitate medicine access in their countries.¹¹² Two World Health Assembly Resolutions¹¹³ in May 2001 which referred to access to essential medicines were also initiated to support the agenda of the African Group and developing country allies.

2.4 The Doha Declaration on TRIPS and Public Health

In April 2001, WTO Members agreed to hold a special session of the TRIPS Council. The special session was called to discuss the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying the flexibilities to which Members are entitled to and, in particular, to establish the relationship between intellectual property rights and access to treatment. The African Group submitted a proposal containing draft text of a ministerial declaration on the TRIPS Agreement and public health at the TRIPS Council meeting of June

¹⁰⁹ The Court case was referred to in a proposal submitted by the African group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela before the TRIPS Council in June 2001. See document IP/C/W/296.

¹¹⁰ The African Group as the name suggests is a coalition of African countries who had developed one common negotiating position on a range of trade issues, not least of all on intellectual property and public health in 2001. At the time, the most active members of the African Group on matters of intellectual property and treatment access included a number of eastern and southern African countries such as Kenya, Tanzania, Zambia, Zimbabwe and South Africa. As of May 2014, the African Group had a membership of 42 countries. An updated list of Members is [Online] Available at: http://www.wto.org/english/tratop_e/dda_e/negotiating_groups_e.htm

¹¹¹ On 19 June 2001, the WTO TRIPS Council held its first meeting on the implications of TRIPS on access to medicines. In this meeting and a subsequent one held on 25 July 2001, it became clear that developing countries were determined to obtain clarity on instances under which countries could use the flexibilities contained in the TRIPS Agreement to access more affordable treatment.

¹¹² The exact text of the agreement is available on the Human Rights Commission Website [Online] Available: [http://www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.SUB.2.RES.2001.21.En?Opendocument)

¹¹³ WHA54.10 Resolution calling for the scaling up of the response to HIV/AIDS and WHA 54.11 entitled “WHO Medicines Strategy”.

2001¹¹⁴ in partnership with a coalition of developing countries. The proposal contained a political chapeau developed to ensure that the TRIPS Agreement did not undermine the right of WTO Members to formulate their own public health policies, as well as practical clarifications for provisions in the TRIPS Agreement on compulsory licensing, parallel importation, and production for export to a country with insufficient production capacity amongst others.¹¹⁵ In response, at a Special Session of the TRIPS Council,¹¹⁶ the US, Japan, Switzerland, Canada and Australia circulated the summary of a non-paper highlighting the importance of intellectual property protection for the R&D of medicines and in so doing, proposed alternative language.¹¹⁷

It became clearer to the US delegation that public pressure, especially in the face of the South African Court case, required that the matter be addressed at the Doha Ministerial Conference scheduled to take place in November 2001. This led to the final process of drafting being assigned to the Chair of the General Council at the WTO, Ambassador Harbison, with the understanding that he would work in consultation with the then Chair of the TRIPS Council, Ambassador Chidyausiku from Zimbabwe.¹¹⁸ This development, coupled with the anthrax attacks in the US in October 2001¹¹⁹ helped to pressure the US into accepting the need for a declaration on intellectual property and public health. On 27 October 2001, the US made a proposal to place a moratorium on bringing any sub-Saharan African countries before dispute settlement for matters relating to TRIPS.¹²⁰ The attempt by the US to offer a geographical exemption was rejected by Members and eventually, the Doha Declaration on TRIPS and Public Health¹²¹ was adopted towards the end of

¹¹⁴ WHO (2002) “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, Geneva [Online] available: http://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf. See also, Kongolo, T (2003) ‘TRIPS, the Doha Declaration and Public Health’, 6(2) Journal of World Intellectual Property 373 at 374.

¹¹⁵ Refer to WHO (2002) at 3 for more details on the proposal made by the African Group.

¹¹⁶ Held on 19 September 2001.

¹¹⁷ For a more detailed discussion of the non-paper, see Bridges Weekly Trade News Digest Volume 5 number 32 of 25 September 2001 [Online] available: <http://ictsd.org/i/news/bridgesweekly/6639/>

¹¹⁸ Abbott F, (2002) ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’, 5 (2), JIEL 469 at 486.

¹¹⁹ In the aftermath of the September 11 2001 terrorist attacks, a number of US government buildings in Washington D.C. were contaminated with an anthrax-laced powder, resulting in a number of deaths and serious illnesses. In response to the possibility that bioterrorism would need a broader public health response, the US Secretary of Health and Human Services in October 2001 revealed that he had threatened R&D based company Bayer with a compulsory license for its patented product ciprofloxacin, if the company did not meet the government’s demand for a reduced price. After this episode, it became untenable for the US government to argue that there was no need for a declaration on intellectual property and public health.

¹²⁰ Ibid Abbott (2002) at 489.

¹²¹ The Doha Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/W2, 14 November 2001.

the Ministerial meeting in Qatar.¹²² This achievement was widely viewed as a victory for developing countries with high disease burdens¹²³ particularly those in eastern and southern Africa. The Doha Declaration recognised the gravity of the public health crisis facing many of the then 142 WTO Members, particularly among the developing countries and LDCs and emphasised the impact of HIV, TB and malaria on its Members. It also affirmed that the TRIPS Agreement does not and should not prevent measures taken by countries to protect public health and that the TRIPS Agreement should be interpreted in a manner supportive of WTO Members' rights to protect public health and to promote access to medicines. It also recognised the rights of each WTO Member to determine what in its opinion, constitutes a national emergency or a situation of extreme urgency. The Doha Declaration also extended the rights of LDCs to postpone the granting of pharmaceutical patents in their countries until 2016¹²⁴ or a subsequent date to be agreed by WTO Members.

While the Doha Declaration re-affirmed the rights of countries to issue compulsory licenses for the local production of medicines, an issue of great importance for countries without significant pharmaceutical manufacturing capacity remained unresolved. Article 31(f) of the TRIPS Agreement required that any product manufactured under compulsory license would have to be produced predominantly for the supply of the domestic market authorising such use. This meant that even where hypothetically, a developing country like India, Brazil or South Africa issued a compulsory license for the manufacture of an essential medicine, it could only export less than 50 percent of the supply to any other country.¹²⁵ This left the majority of developing countries and LDCs, particularly those with high levels of disease burden including many in eastern and southern

¹²² The WTO's 4th Ministerial conference was held in Doha, Qatar from 9-14 November 2001 and was the launch of the as yet, un-concluded round of trade talks known as the "Doha Development Agenda." The Doha Ministerial meeting provided WTO Members with a mandate to negotiate on key issues of agriculture, non-agricultural market access (NAMA) and services. The Doha round has not yet been concluded despite subsequent WTO ministerial meetings in Cancun in 2003, Geneva in 2004, Hong Kong in 2005 and Geneva in 2009.

¹²³ Drahos P, (2002) 'Developing Countries and International Intellectual Property Standard Setting', 5 (5) Journal of World Intellectual Property 765 at 781.

¹²⁴ Paragraph 7 of the Doha Declaration. For further discussion on the implications of the Doha Declaration, refer to Sun H, (2003) 'Reshaping the TRIPS Agreement Concerning Public Health: Two Critical Issues' JIEL 37(1) 163-197, Kluwer Law International.

¹²⁵ Abbott F, (2001) 'The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference' Occasional paper 7, Quaker United Nations Office- Geneva at 13, suggested that before the Doha Ministerial took place that "Some developing Member may wish to pool productive resources and create regional supply facilities operating under compulsory license, with no single predominant market."

Africa with no tangible solution to address their public health crises. Paragraph 6 of the Doha Declaration sought to address this situation by explicitly recognising that WTO Members with insufficient or no pharmaceutical manufacturing capacity had virtually no practical use for compulsory licensing provisions under Article 31 of TRIPS. It also tasked the TRIPS Council to find an expeditious solution to this problem by the end of 2002.¹²⁶

The 21 months it took WTO Members to find the ‘expeditious solution’ resulted in some of the most acrimonious disagreements between developed and developing countries since the establishment of the WTO.¹²⁷ Unlike the negotiations which established the TRIPS Agreement, there was a greater involvement of civil society groups who were sympathetic to developing country interests.¹²⁸ Organisations such as the Consumer Project on Technology (CPTech), MSF, Third World Network (TWN) Health Action International (HAI) and Oxfam to name a few, played an important role in support of the African Group and other developing countries at the WTO by advocating for public health concerns while keeping the public informed of developments of the negotiations in Geneva.¹²⁹

According to Matthews,¹³⁰ negotiations to resolve the now termed “paragraph 6 problem” concerned the scope of diseases to be included in an eventual agreement; the countries to be beneficiaries of an agreement on access to essential medicines either as importers or exporters of affordable essential medicines; a possible waiver of Article 31(f) of TRIPS; a moratorium on complaints to the WTO Dispute Settlement Body (DSB) in relation to Article 31(f) and finally, the possibility of an Article 30 solution. The debate around the scope of diseases to be covered by the paragraph 6 solution was a contentious one with the US insisting that a paragraph 6 solution only

¹²⁶ Correa C, (2004) ‘Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’, WHO, 2004.

¹²⁷ Avafia T, (2005) ‘TRIPS and Public Health: the unresolved Debate’, Tralac Trade Brief 2, University of Stellenbosch Printers.

¹²⁸ Matthews D, (2004) ‘Is History Repeating itself? The Outcome of Negotiations on Access to Medicines, the HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation’ University of Warwick, LGD (1).

¹²⁹ See Matthews D, (2006) ‘NGOs, Intellectual Property Rights and Multilateral Institutions’, Queen Mary Intellectual Property Institute, University of London [Online] Available:

<http://www.ipngos.org/Report/IP-NGOs%20final%20report%20December%202006.pdf>

Some of these NGOs had provided negotiating and policy advice to developing countries even in the lead up to the Doha Declaration.

¹³⁰ Ibid Matthews (2004) at 6.

apply to medicines for HIV, TB and malaria and to the exclusion of “lifestyle” or non-communicable diseases (NCDs) such as diabetes, hypertension and cardio-vascular disease, while developing countries (the African Group in particular) maintained that a solution be adopted to for the importation of all medicines deemed necessary by a country to address public health concerns.¹³¹ The African Group was heavily involved in the negotiations around the paragraph 6 solution.¹³²

Despite the production of a draft by Ambassador Motta, the then Chair of the TRIPS Council to at the last TRIPS Council meeting in December 2002, the US alone refused to accept the “Motta Draft” on the basis that the proposed language would allow the importation of generic medicines well beyond those required to treat HIV, malaria and TB.¹³³ After further meetings at the TRIPS Council in January, February and June 2003 and with sustained advocacy efforts by international NGOs,¹³⁴ reports began to surface that the US would be prepared to agree to a compromise on the scope of diseases if it could obtain a guarantee that the solution would only be used by LDCs and developing countries with high disease burdens as well as assurances that health technologies imported under compulsory license would not be re-exported for financial gain.¹³⁵

¹³¹ Ibid Matthews (2004).

¹³² During the negotiations on this matter between November 2001 and August 2003, The African Group for instance, in WTO Document IP/C/W/351 proposed a moratorium on bringing complaints at the WTO Dispute Settlement Body against developing countries who may have violated Article 31(f) of TRIPS. When the then TRIPS Council Chairman released a compromise text on 16 December 2002 in an attempt to resolve the impasse at the WTO TRIPS Council, Kenya, on behalf of the African Group made the following statement:

“The African Group is disappointed and frustrated by the progress made so far. The group feels if the discussions continue on the same line as they have been conducted to date, then it is unlikely that the desired solution will be forthcoming, and particularly one meant to address the public health problems afflicting Africa. Members may wish to seriously reflect on the reasons why the African group raised the issue in the TRIPS Council prior to the Doha conference and their subsequent expectations after the issue in the Doha [Declaration] as stated in the various communications of the TRIPS Council. This probably gives them a better understanding of the nature of the solution Africa expects.”

¹³³ The scope of diseases was cited by the US as the sole reason why it could not agree with the Motta Text. See IP/C/M/38, 5 February 2003.

¹³⁴ For a list of letters, statements and press releases by CPTech and other NGOs over the duration of the negotiations, refer to: <http://www.cptech.org/ip/wto/p6/>

¹³⁵ See for instance, a story from the Bridges Weekly digest of 3 July 2007 Volume 7 number 24 ‘US rumoured to consider change in tactic on TRIPS and Health’ [Online] available: <http://ictsd.org/i/news/bridgesweekly/6927/>

2.5 The 30 August 2003 Agreement and the 2005 Decision to Amend Article 31 of TRIPS

The next chair of the TRIPS Council, Ambassador Menon of Singapore, met with a small group of key countries including the US, Kenya, Brazil, South Africa and India and succeeded in producing a draft Decision. The WTO General Council was presented with a final draft of the Decision which was adopted on 30 August 2003,¹³⁶ preceded by the reading of a statement by the Chairperson of the WTO General Council, the legal application of which is still a matter of debate between WTO Members. The Decision provides a legal pathway for countries with manufacturing capacity to export medicines to countries with insufficient or no pharmaceutical manufacturing capacity by establishing a mechanism to waive the application of Article 31(f) for exporting countries, and Article 31(h) for the importing countries.¹³⁷

The Decision¹³⁸ requires eligible importing countries¹³⁹ with the exception of LDCs to notify the TRIPS Council of their pharmaceutical needs and an assessment that they are unable to meet these needs through local production. Next,¹⁴⁰ eligible importing countries are required to notify the TRIPS Council of:

- (i) the names of the needed product; and
- (ii) the expected quantities (which could be expressed by the number of specific dosages, amount of active pharmaceutical ingredients or patients to be treated).

¹³⁶ 'Cheap Drugs Deal Agreed as US lifts Veto' Frances Williams, *Financial Times*, 1 September 2003, 8. Refer to *The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/C/W/405, 30 August 2003 [Online] Available:

http://www.wto.org/english/tratop/trips_e/implem_para6_e.htm.

¹³⁷ For a paragraph by paragraph discussion of the content of the 30 August Decision, refer to UNCTAD-ICTSD, 2005, "Resource Book on TRIPS and Development", Cambridge University Press at 484-5.

¹³⁸ Paragraph 2.

¹³⁹ A number of industrialised countries, namely, Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the UK and the US, declared that they would not use the Waiver.

A second set of countries including the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia reserved the right to use the Agreement in the event of a national emergency or a situation of extreme urgency until they had officially acceded to the European Union on 1 May 2004, after which they would not use the Waiver.

A third set of countries agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: China, Hong Kong; Israel; Korea; Kuwait; Macao; Mexico; Qatar; Singapore; Chinese Taipei; Turkey; and the United Arab Emirates.

¹⁴⁰ See Correa (2004) for a discussion on the eligibility of countries to utilise the Agreement, in particular at 15-20.

Where a valid patent on the product exists in the importing country, the eligible importing country should indicate that it has either issued or intends to issue a compulsory license. A license is to be issued according to the regulations of Article 31 of TRIPS.¹⁴¹

The Decision also requires the exporting country to issue a compulsory license in compliance with the provisions of Article 31 of TRIPS. These obligations include the duty to negotiate with the patent holder for a voluntary license to be issued on reasonable terms and conditions and within a reasonable amount of time. The Decision also requires that the compulsory license be issued only to supply the particular importing country in question, and that the entirety of the product be exported. In addition, there are some safeguards that must be met by the exporting country in order to prevent the diversion of the pharmaceuticals.¹⁴² Aside from notifying the TRIPS Council of the destination, quantities to be supplied and the duration of the license, the exporting country should also ensure that the medicines can be identified by special packaging and/or labelling of the packages as well as any special colouring and/or shape of the medicines to ensure that they are easily distinguishable.¹⁴³ The exporting company is expected to post a notification on a website administered by the WTO Secretariat with information on (i) the quantities being supplied to each destination, and (ii) the distinguishing features of the product(s). In addition, the exporting country is expected to post information on the WTO administered website with the following details:

- the name and address of the licensee;
- the product(s) for which the licence has been granted;
- the quantity(ies) for which it has been granted;
- the country(ies) to which the product(s) is (are) to be supplied;
- the duration of the licence;
- the address of the web site where the supplier will post the information mentioned above.

¹⁴¹ Correa (2004) at 15.

¹⁴² It should be remembered that the risk of medicines destined for one market either being diverted en route, or being re-sold by the importing country, was one of the two primary concerns voiced by the US during the TRIPS Council negotiations from early 2002 to August 2003, the other one being the scope of diseases.

¹⁴³ See UNCTAD-ICTSD (2005) at 485.

Paragraph 6 of the 30 August Decision also introduces an additional waiver by allowing WTO Members that belong to regional economic communities ¹⁴⁴ where at least half the members are LDCs, to further export products that have been manufactured or imported under a compulsory license to other countries that are members of that regional group.¹⁴⁵ The mechanism could in theory, result in countries co-operating to establish economies of scale, which, in turn, increases the likelihood of bulk purchasing.¹⁴⁶ Paragraph 6 of the 30 August mechanism was clearly included with African countries in mind as the only regional economic communities in the world eligible are the SADC, the EAC, the Economic Community of West African States (ECOWAS), the Economic Community of Central African States (ECCAS) and the Common Market for Eastern and Southern Africa (COMESA).

As noted earlier, there continues to be a lack of consensus among WTO Members over the interpretation of the Statement read by then WTO General Council Chairman, Ambassador Castillo (the Chairperson's Statement).¹⁴⁷ In summary, the statement stresses that the decision will be interpreted and implemented on a good faith basis "*and not as an instrument to pursue industrial or commercial policy objectives.*" It also urges countries making use of the mechanism to take all steps within their influence to prevent the diversion of the medicines imported/exported, while referring to some best practice examples based on existing anti-trade diversion detections already in use by donor pharmaceutical companies.¹⁴⁸

Despite considerable criticism from civil society groups and treatment activists questioning the practical use of an administratively cumbersome mechanism¹⁴⁹ and a statement in early December

¹⁴⁴ Classified as a regional trade agreement as defined by Article XXIV of the GATT of 1994.

¹⁴⁵ Matthews D, (2006) 'From the August 30, 2003 WTO Decision to the December 6, 2005 agreement on an amendment to TRIPS: improving access to medicines in developing countries?' I.P.Q. No. 2, Sweet & Maxwell Ltd and Contributors.

¹⁴⁶ Vandoren P, and Eeckhaute J, (2003) 'The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Making it work', 6(6) Journal of World Intellectual Property 779 at 783.

¹⁴⁷ The Chairperson's statement is [Online] Available electronically:

http://www.wto.org/english/news_e/news05_e/trips_319_e.htm

¹⁴⁸ See Abbott F, and Reichman J, (2007) 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions' Journal of International Economic Law 10 (4), Oxford University Press, 921-987 at 945-946 for a more detailed discussion on the Chairperson's Statement.

¹⁴⁹ For a comprehensive list of press-releases, statements and documents by NGOs criticizing the effectiveness of the 30 August 2003 Decision while raising doubts as to the wisdom of making it a permanent amendment to the TRIPS Agreement, refer to the CPTECH website [Online] Available: <http://www.cptech.org/ip/wto/p6/index.html>

2005 urging WTO Members to refrain from accepting the 30 August Decision as the final solution to the paragraph 6 problem¹⁵⁰ and despite the fact that no country until that point, had attempted to use the mechanism, on 6 December 2005, consensus was reached at the TRIPS Council to turn the 30 August 2003 Decision (which was a temporary waiver) into an amendment of Article 31 of TRIPS thus signifying the first time in the history of the WTO that a primary agreement was to be amended. This outcome was viewed by many activists and NGOs as a poor return for developing countries including the African Group considering how much negotiating capital had been invested in finding a practical and usable mechanism for countries with no or insufficient manufacturing capacity to adequately address their public health crises.¹⁵¹ WTO Members initially set a deadline of 1 December 2007 to ratify the decision to permanently amend Article 31 of TRIPS.¹⁵² Despite four extensions of the deadline to 31 December 2009,¹⁵³ 31 December 2011,¹⁵⁴ 31 December 2013,¹⁵⁵ and 31 December 2015¹⁵⁶ or a subsequent date as agreed by WTO Members, it has not been ratified by enough WTO Members for the amendment to the TRIPS Agreement to enter into force.¹⁵⁷

¹⁵⁰ A joint statement on TRIPS and Health urged countries not to enter into an agreement which had not been shown to be a useful tool for developing countries to increase access to essential medicines. The statement also encouraged countries to focus on finding a mechanism that really would facilitate access to medicines and pointed out that until a permanent solution was available, developing countries could still utilize the 30 August Decision. For the complete statement, refer to: ‘WTO Members should reject bad deal on medicines’ joint statement by NGOs on TRIPS and Public Health, December 3, 2005, [Online]. Available:

www.cptech.org/ip/wto/p6/ngos12032005.html

¹⁵¹ The 6 December 2005 Decision on the Amendment of the TRIPS Agreement (WT/L/641) is available at: http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm NGOs such as MSF who, at the time, had more than 29 000 patients on antiretroviral therapy in 29 countries were highly critical of the Decision on the basis that “*the drug by drug, country by country decision making process discourages economies of scale and slows down price reductions*” Refer to the MSF Press Release of 12 December 2005 entitled ‘WTO Sacrifices Access to Medicines Before Hong Kong Ministerial Meeting’ for a more detailed critique of the Decision to Amend the TRIPS Agreement [Online] Available: http://www.msf.org/msfinternational/invoke.cfm?objectid=1E9AC826-E018-0C72-095365D44BB1AE4C&component=toolkit.pressrelease&method=full_html

¹⁵² See Paragraph 2 of the Decision.

¹⁵³ See WT/L/711

¹⁵⁴ See WT/L/785.

¹⁵⁵ WT/L/829.

¹⁵⁶ WT/L/899.

¹⁵⁷ While at least two thirds of WTO Members are required to ratify the decision for the permanent amendment to take place, as of October 2014, 53 countries (excluding Croatia which has subsequently joined the EU) and the EU had ratified the amendment. Assuming that the EU’s ratification constitutes an additional 28 ratifications, this still leaves the Amendment at around 80 countries, significantly short of the required 106 ratifications based on the WTO’s membership of 160 countries as of October 2014.

Starting with Zambia in August 2009, a growing number of African Group Members including countries in eastern and southern Africa have ratified the amendment to Article 31 of TRIPS.¹⁵⁸ The reasons for this may lie in developments outside of the realm of the TRIPS Agreement. After the G-8 countries endorsed its establishment in Genoa, Italy in 2001, the GFATM was established in January 2002 to finance the responses of the three most deadly epidemics in LMICs and to increase donor co-ordination, country ownership and transparency in health financing. Less than 12 years later, the GFATM had disbursed more than US\$ 22 billion in more than 1050 grants across 151 countries.¹⁵⁹ PEPFAR, which was established in 2003 by President Bush to respond to the growing AIDS crisis in Africa, has disbursed in excess of US\$ 41 billion was disbursed between 2003 and 2014 across approximately 60 countries. The largest recipients of GFATM and PEPFAR funding have naturally been the countries with the highest disease burdens in eastern and southern Africa. Of the countries in the region who have ratified the agreement to amend Article 31 of TRIPS, Zambia has received more than US\$ 750 million between 2002 and 2014 from the GFATM, and more than US\$ 250 million from PEPFAR, while Botswana received US\$ 17 million and US\$ 554 million, Rwanda, US\$ 920 million and US\$ 394 million and Uganda, US\$ 526 million and US\$ 898 million in funding from the GFATM and PEPFAR respectively.

This influx of funding from multilateral and bilateral financing sources would have gone a long way in reducing the great sense of urgency that propelled members of the African Group in the early 2000s to find a solution that would enable the importation of generic medicines by countries without sufficient pharmaceutical manufacturing capacity. The funding received by countries in eastern and southern Africa in response to their public health crises supports the first hypothesis advanced in chapter one, namely, that the incorporation and use of public health related TRIPS flexibilities has not been needed to treat patients in eastern and southern African countries because the majority of patients are on first-line ART which is financed by multilateral funding mechanisms. As will be discussed later in the thesis, this is not a sustainable situation given the anticipated decline of multilateral funding for AIDS responses in Africa

¹⁵⁸ As of October 2014, the eastern and southern African countries that had ratified the Agreement were Botswana, Rwanda, Uganda and Zambia.

¹⁵⁹ See USAID (2013) 'The Global Fund to Fight AIDS, Tuberculosis and Malaria' Issue Brief [Online] Available: http://www.usaid.gov/sites/default/files/documents/1864/Gfatm_brief.pdf

2.6 Recent Developments on the Enforcement of Intellectual Property and Potential Implications on Essential Medicine Access in Eastern and Southern Africa

2.6.1 Heightened Intellectual Property Protection through Bilateral Trade and Investment Agreements

As discussed above, the adoption of minimum standards of intellectual property protection and enforcement ushered in by the TRIPS Agreement resulted in a significant loss of policy space available to LMICs to facilitate access to medicines through domestic legislation. The erosion of policy space has been compounded by the proliferation of bilateral and regional trading agreements which, in some instances, have undermined the use of TRIPS flexibilities for public health purposes.¹⁶⁰ An increase in bilateral and regional trade agreements has been traced back to the unsuccessful conclusion of the WTO Seattle Ministerial of 1999, which prompted initially, the US and EU, and more recently, other developed countries such as Japan and trading blocs such as the European Free Trade Area (EFTA)¹⁶¹ to accelerate bilateral trading activity¹⁶² by making use of Article XXIV of the GATT.¹⁶³

The main objective of Article XXIV was to prevent RTAs from becoming obstacles to the development of multilateral trade, and turning them into stepping-stones towards open trade.¹⁶⁴ However, developed countries and trading blocs that have concluded FTAs which could negatively impact medicine access in developing countries include the US, Japan, EU and the EFTA trade bloc.¹⁶⁵ The new generation of FTAs have also extend beyond the traditional trade negotiating

¹⁶⁰ According to the WTO Secretariat, as of late 2014 January 2014, almost 600 RTAs (counting goods, services and accessions separately) had been received by the GATT/WTO, of which, 377 were in force.

¹⁶¹ EFTA Member States include Iceland, Lichtenstein, Norway and Switzerland.

¹⁶² The pursuit of FTAs as a replacement to stalling multilateral negotiations has also been a priority for EFTA as well as the European Union which has sought to replace the asymmetrical Cotonou Trading Agreement between itself and its former colonies with Economic Partnership Agreements (EPAs) at various stages of conclusion with the African, Caribbean and Pacific (ACP) States.

¹⁶³ Article XXIV sets the conditions under which Regional Trade Agreements (RTAs) can derogate to the Most Favoured Nation (MFN) principle contained in Article I of the GATT.

¹⁶⁴ See Lang R, (2006) 'Re-negotiating GATT Article XXIV – A priority for African countries engaged in North-South trade agreements', African Trade Policy Centre no. 33 Economic Commission for Africa [Online] Available: <http://www.uneca.org/ATPC/Work%20in%20progress/33.pdf>

¹⁶⁵ Refer to www.bilaterals.org for a comprehensive catalogue of all stories, press-releases and analytical papers involving FTAs that have been negotiated as well those currently being negotiated. Details of the FTAs being negotiated by these four countries and trading blocs is available on this website.

agenda —trade in goods and services— to cover the so-called “new generation” trade policy issues.¹⁶⁶

The most obvious consequences of ‘TRIPS plus’ provisions with implications on access to affordable treatment include:

- (a) The potential extension of patent protection beyond the 20 year minimum required by TRIPS;¹⁶⁷
- (b) Conferring a new responsibility onto Drug Regulatory Authorities, (DRAs) most of whom have limited knowledge of intellectual property, to consider the patent status of drugs before granting marketing authorization to manufacturers of generic medicines;¹⁶⁸
- (c) The restricting of reliance on access to data on pharmaceutical products for DRAs, which generic companies traditionally rely on to prove the efficacy and safety of their products, which results in the significant slowing down of the registration, and subsequently, the entry into the market of generics in some countries;¹⁶⁹

¹⁶⁶ Provisions present in bilateral trading agreements for which there is no corresponding operational WTO multilateral agreement, include investment, government procurement, competition policy, environmental regulations and labour standards. Refer to Kawai M, and Wignaraja G, (2009) ‘Asian FTAs: Trends and Challenges’. Asian Development Bank Institute Working Paper 144, Tokyo. [Online] Available:

<http://www.adbi.org/working-paper/2009/08/04/3256.asian.fta.trends.challenges/>. See also Abbott F, (2004) ‘The Doha Declaration on the TRIPS Agreement and Public Health and the contradictory Trend in Bilateral and Regional Free Trade Agreements’ Occasional Paper 14, Quaker United Nations Office. [Online] Available: <http://www.geneva.quino.info/pdf/OP14Abbottfinal.pdf>

¹⁶⁷ For instance, Article 23(a) of the US-Jordan Agreement on the Establishment of a Free Trade Area states that:

“With respect to pharmaceutical products that are subject to a patent...each Party shall make available an extension of the patent term to compensate the patent holder for unreasonable curtailment of the patent term as a result of the marketing approval process.”

¹⁶⁸ See Chapter 16:10.4 of the US-Peru FTA which states that:

“Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, the Party may implement the provisions of paragraph 3 by:

(a) implementing measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the product or its approved method of use during the term of that patent, unless by consent or acquiescence of the patent owner”.

¹⁶⁹ For example, Article 15 of the US -Central American Free Trade Agreement (CAFTA) which comprises of Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua) is a marked departure from TRIPS. The originator of the data in order to prevent third parties from relying on his data, does not have to prove unfair commercial practices required by Article 39 of TRIPS. Furthermore, the FTA creates a previously non-existent requirement for the patent holder to consent or acquiesce at the least, before marketing approval for competing generic products is granted.

- (d) The restriction of parallel imports to limited geographical configurations which may prevent LMICs from sourcing generics from the cheapest global supplier;¹⁷⁰
- (e) Limiting patent oppositions;¹⁷¹
- (f) Compelling countries to relax criteria for patentability beyond what is required by Article 27(1) of TRIPS;¹⁷² and
- (g) Investment provisions which regard the use of public health related TRIPS flexibilities both as an expropriation of property which entitles the patent owner to adequate and effective compensation as well as a violation of national treatment rules both of which can be used as grounds to litigate against government authorities.¹⁷³

The EU's EPA negotiations with various ACP countries are still mostly in the process of being finalized with a number of Interim Economic Partnership Agreements (IEPAs) having been concluded by the end of 2013.¹⁷⁴ Negotiations between the EFTA countries and the Southern

¹⁷⁰ Chapter 15:9 of the US-Morocco FTA obliges the parties to the Agreement to “provide that the exclusive right of the patent owner to prevent importation of a patented product, or a product that results from the patented process, without the consent of the patent owner shall not be limited by the sale or distribution of that product outside its territory- A party may limit application of this paragraph to cases where the patent owner has placed restrictions on import by contract or other means.”

¹⁷¹ Chapter 15:8.4 of the US FTA with Oman requires that:

“Each Party shall provide that a patent may be revoked only on grounds that would have justified a refusal to grant the patent ... Where a Party provides proceedings that permit a third party to oppose the grant of a patent, a Party shall not make such proceedings available before the grant of the patent.”

¹⁷² Chapter 14:8.2 of the US Bahrain FTA obliges the parties to the Agreement to make patents available for plant inventions. In addition, the Parties confirm that patents shall be available for any new uses or methods of using a known product, including products to be used for particular medical conditions.

¹⁷³ See Perkams M, and Hosking J, (2009) ‘Protection of Intellectual Property Rights Through International Investment Agreements: Only Romance or True Love?’ *Transnational Dispute Management Journal*, 2, See also Chapter 10 of the US DR-CAFTA FTA for example provides for both the national treatment of investors in the signatory countries as well as compensation for expropriation of property, although the latter explicitly notes that compulsory licensing does not constitute expropriation. The chapter is silent on the use of other TRIPS flexibilities however. Similar provisions have been signed in FTAs involving the US and Oman, Australia, Chile and others. A prime example of how investment provisions can result in legal challenges against a state involves an arbitration filing brought by Eli Lilly against Government of Canada for alleged violations of its obligations under the North American Free Trade Agreement (NAFTA) when it invalidated patents for two of its pharmaceutical products. The requested remedy is payment in the amount of 500 million Canadian dollars, equivalent to US\$ 460 million. See *In the Arbitration under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement: Eli Lilly v. Government of Canada* [Online] Available: <http://infojustice.org/wp-content/uploads/2013/09/Eli-Lilly-Notice-of-Arbitration-September-12-2013.pdf>

¹⁷⁴ The negotiation process for the EPAs has been a controversial and fractious process in eastern and southern Africa, where the EPA negotiations are taking between the EU and three blocs of countries. The EAC Partner States have initialled but not yet signed an interim EPA (IEPA), while the SADC countries in this case comprising of Botswana, Lesotho, Mozambique, Swaziland and South Africa have signed the IEPA with the exception of Angola and Namibia.

African Customs Union (SACU)¹⁷⁵ excluded intellectual property relating to public health from the text of the final agreement when agreement was signed in June 2006 following an advocacy campaign by treatment activists.¹⁷⁶

The US had entered into negotiations with the SACU countries, with intellectual property as one of the substantive negotiating issues.¹⁷⁷ Despite several trade rounds, the negotiations were not concluded, primarily because of a lack of harmonisation in negotiating position and policy amongst the SACU countries, and a reluctance on the part of SACU negotiators to enter into an FTA which would impact adversely on their developmental objectives.¹⁷⁸ The FTA talks were downgraded to trade and investment negotiations in 2006 which resulted in the signing of a Trade, Investment and Development Cooperation Agreement (TIDCA) between the parties in July 2008, in which there appear to be no provisions that may impact negatively on access to treatment in the region at this stage.¹⁷⁹

2.6.2 The Emergence of ‘TRIPS Plus’ Measures Through the Enforcement and Anti-Counterfeiting Regulations and Legislation

Of greater consequence to countries in eastern and southern Africa is the emergence of heightened intellectual property enforcement through multilateral developments, regional arrangements and national legislation. Part III of the TRIPS Agreement contains general obligations, rules on civil and administrative procedures, provisional measures, special requirements related to border measures, and criminal procedures.¹⁸⁰ Article 41 of TRIPS in setting out the main principles regarding enforcement, requires that:

A third set of countries are negotiating the EPAs as an a central and southern African configuration and include the Democratic Republic of the Congo, Madagascar, Malawi, Mauritius, Zambia and Zimbabwe.

¹⁷⁵ The SACU countries comprise of Botswana, Lesotho, Namibia, South Africa and Swaziland.

¹⁷⁶ See ICTSD news article dated 9 March 2005 entitled ‘Southern African Countries Reject “TRIPS Plus” Demands in FTA Negotiation’ [Online] Available: <http://ictsd.org/i/ip/39047/>

¹⁷⁷ Avafia T, (2004) ‘The Potential Impact of the Proposed US-SACU Free Trade Agreement on public health in southern Africa’ Tralac, working paper 6 at 17.

¹⁷⁸ See Business Day Report of 16 November 2006 ‘US all-or-nothing position derails free trade talks’ [Online] Available: http://www.bilaterals.org/article.php3?id_article=6489

¹⁷⁹ A copy of the TIDCA is [Online] available at: <http://www.sacu.int/docs/tidca/agreement.pdf>

¹⁸⁰ See Tekeste Biadgleng E, and Munoz Tellez V, (2008) ‘The Changing Structure and Governance of Intellectual Property Enforcement’, Research Paper 15, South Centre, Geneva, page 2.

- procedures must be available under domestic laws to permit effective action against infringement of intellectual property rights;
- enforcement procedures must be applied in such a manner as to safeguard against abuse and to avoid the creation of barriers to legitimate trade;
- procedures must be fair and equitable and not unnecessarily complicated or likely to cause unwarranted delays;
- courts and administrators must base their decisions only on evidence available to all parties, and these should preferably be written and reasoned;
- there must be some form of review for decisions handed down by first instance administrative or judicial agencies; and
- Members are under no obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general.¹⁸¹

The number of multilateral institutions that have been involved in policy and norm setting on intellectual property enforcement in recent years has grown and now includes the World Customs Organization (WCO), WIPO, the WHO, the WTO and Interpol. The US and the EU have also taken steps to strengthen the enforcement of intellectual property rights in third countries through regional and bilateral trade agreements.¹⁸² There are efforts in various multilateral fora to enhance the levels of intellectual property enforcement to extend beyond the minimum standards as set out in the TRIPS Agreement. For example, there are initiatives to authorize *ex officio* actions by customs authorities to suspend goods suspected of infringing intellectual property rights, as well as providing for seizure of goods intended not only for import, but for goods in transit and for export, which is not required by Article 51 of TRIPS.¹⁸³ The EU chose to extend this requirement

¹⁸¹ Ibid Tekeste Biadleng and Munoz Tellez at 5.

¹⁸² Ibid Tekeste Biadleng and Munoz Tellez.

¹⁸³ Sell S, (2008) 'The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts: the state of play', Occasional Papers No 1, IQsensato, Geneva. [Online] Available: http://www.twinside.org.sg/title2/intellectual_property/development/research/SusanSellfinalversion.pdf. See also Tekeste Biadleng and Munoz Tellez (2008) as well as Tandon Y, (2008) Editorial: 'WIPO, WCO, intellectual property and border guards.' South Bulletin, 2008, Issue 15. South Centre, Geneva. According to Park, Article 51 requires countries to allow customs officials, upon the valid application of a right holder, to suspend suspected counterfeit trademark and pirated copyright goods from importation into the country. This obligation does not extend to export goods or goods in transit, and requires the affirmative application by the right holder through the proper judicial or administrative channels.

to goods in transit,¹⁸⁴ which led to the seizure of at least 17 shipments of generic medicines from India in transit in the EU *en route* to a number of developing countries on the suspicion of being counterfeit medicines.¹⁸⁵ It has transpired that none of the seized shipments were counterfeit despite their detainment and in some instances, return to the country of origin, India. These have led to the issue of counterfeit medicines being debated, without conclusion, at the WHO's World Health Assembly and the TRIPS Council.

Aside from the seizure of medicines in transit on the suspicion of being counterfeit, a number of countries in eastern and Southern Africa have either adopted or are in the process of drafting or adopting regional and national regulations on anti-counterfeiting, which could have a detrimental impact on access to generic medicines in the region. In the EAC region, Kenya passed an Anti-Counterfeiting Act in December 2008.¹⁸⁶ The Act was invalidated through a constitutional challenge¹⁸⁷ brought by three petitioners living with HIV in which the Court found that a number of provisions of the Act such as Section 2 relating to the definition of counterfeiting,¹⁸⁸ Section 32 dealing with offences and Section 34(1) which deals with the power to seize goods suspected of being counterfeit, exceed the minimum requirements of TRIPS.¹⁸⁹ Ruling on the definition of counterfeiting in the Act, the High Court held that:

¹⁸⁴ European Customs Regulation (Council Regulation (EC) No 1383/2003 of 22 July 2003.

¹⁸⁵ See Seuba X, (2009) 'Border Measures Concerning Goods Allegedly Infringing Intellectual Property Rights: The Seizures of Generic Medicines in Transit' Working Paper, International Centre for Trade and Sustainable Development, Geneva, Switzerland, [Online] Available: http://www.iprsonline.org/New%202009/Seuba_Border%20Measures.pdf

¹⁸⁶ The Anti-Counterfeit Act 13 of 2008.

¹⁸⁷ See the case of *Patricia Asero Ochieng and 2 others v. the Attorney General & Another*, Petition N 409 of 2009, Judgment (2012).

¹⁸⁸ Section 2 of the 2008 Anti-Counterfeit Act defines counterfeiting as:

“taking the following actions without the authority of the owner of any intellectual property right subsisting in Kenya or elsewhere in respect of protected goods-

(a) the manufacture, production, packaging, re-packaging, labelling or making, whether in Kenya or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are identical or substantially similar copies of the protected goods;

(b) the manufacture, production or making, whether in Kenya or elsewhere, the subject matter of that intellectual property, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the protected goods of the said owner or any goods manufactured, produced or made under his licence.

(c) the manufacturing, producing or making of copies, in Kenya or elsewhere, in violation of an author's rights or related.

¹⁸⁹ For a discussion of some of the more problematic sections of the Act, see Von Braun J, (2009) 'New Enforcement Mechanisms Challenge the Legality of Generics in the Name of Public Health: the emergence of anti-counterfeiting legislation in Africa- the cases of Kenya and Uganda' unpublished, on file with author. See also UNDP (2012) 'Anti-counterfeit Laws and Public Health: What to Look Out For' UNDP Discussion Paper [Online] Available:

“It is incumbent on the state to reconsider the provisions of section 2 of the Anti-Counterfeit Act alongside its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of petitioners and others dependent on generic medicines are not put in jeopardy (...)”

In 2014, an Amendment Bill was passed by the National Assembly¹⁹⁰ ostensibly to resolve the misgivings the High Court had regarding the 2008 Act, but had not yet been signed into law by the President as of the end of October 2014. The Bill does not appear to significantly alter the definition of counterfeit which was found to be problematic by the 2012 High Court Decision. It remains to be seen what reaction the amendment of the Act will receive from treatment activists in Kenya and the region.

A draft Counterfeit Goods Bill was also tabled before the Parliament in Uganda in 2008. As is the case with the Kenyan Act, it has been argued that the draft conflates the infringement of different categories of IP into the term “counterfeiting” although each of these categories is distinct under the TRIPS Agreement. In addition, the border measures proposed in the draft extend to all violations of IP rights and to goods imported, exported, and in transit – despite the fact that Article 51 of the TRIPS Agreement only requires border measures for counterfeit trademark goods and pirated copyright goods that are imported.¹⁹¹ Equating the term ‘counterfeit’ with all forms of intellectual property infringement while linking of public health concerns to issues of IP enforcement could have the unintended consequences of impeding the movement of legitimate, high quality generic medicines.

During negotiations which led to the adoption of the TRIPS Agreement, the terms used in relation to counterfeits was limited to “counterfeit trademarks and associated pirated copyright goods”. This is because trademark counterfeiting and copyright piracy can be determined with relatively

[http://www.undp.org/content/dam/undp/library/hiv aids/English/UNDP%20Discussion%20Paper%20-%20\(revised\).pdf](http://www.undp.org/content/dam/undp/library/hiv aids/English/UNDP%20Discussion%20Paper%20-%20(revised).pdf)

¹⁹⁰ The Statute Law (Miscellaneous Amendment) Bill of 2014.

¹⁹¹ According to a meeting report of an expert discussion on the Uganda counterfeit goods Bill of 2009 and the Draft EAC policy on anti-counterfeiting, held in Entebbe, Uganda on 9-10 September 2009 on file with the author.

greater ease, whereas for patent infringements more complex mechanisms are required.¹⁹² For these reason, it is not clear whether the increase in intellectual property enforcement is likely to have the desired effect of stemming the availability of sub-standard medicines in Uganda. It would seem more important for public health goals, to differentiate between sub-standard and counterfeit medicines. As Park¹⁹³ points out:

“It is important to recognize that not including a specific definition of counterfeit medicine does not prevent countries from enacting appropriate criminal sanctions to ensure a safe medicines supply. India’s Drugs and Cosmetics Act, 1940, for instance, does not use the term “counterfeit”, but nevertheless contains criminal provisions relating to drug mislabelling, adulteration, and spurious drugs, and prescribes up to a life sentence for importing, manufacturing or selling any spurious or adulterated drug that is likely to cause death or “grievous hurt”.

Yet a further development in the region funded by the Investment Climate Facility for Africa¹⁹⁴ (ICF), has been the recent formulation of a draft EAC policy on anti-counterfeiting, anti-piracy and other intellectual property rights violations, in a process which has been ongoing since February 2008.¹⁹⁵ A draft anti-counterfeiting Bill emerged in early 2010 which was updated in 2011 and 2013. The Bill is regarded as an attempt to legislate the key elements of the draft Policy. According to the draft EAC policy, the lack of adequate legal framework is a challenge because the current EAC state laws on IPR protection and enforcement are too weak and/or not implemented. The proposed solution is to increase penalties and sanctions, including criminal, against persons in possession of and trade in goods that infringe any IPR. This measure is expected to have a deterrent effect. While little is presently known about the timetable for adoption of the draft policy and Bill, it appears to intend to harmonize and tighten rules with a view to detect counterfeiters, pirates and other intellectual property infringers.

¹⁹² UNCTAD ICTSD 2005, at 610.

¹⁹³ Park C, (2009) ‘Legal Aspects of Defining “counterfeit Medicines”, WHO Regional Office for South-East Asia, New Delhi.

¹⁹⁴ Information about the ICF is available on its website: www.icfafrica.org

¹⁹⁵ According to a 14 February 2008 Newsletter from the East African Business Council [Online] Available: <http://eabc.info/files/newsflashfeb1408.pdf>

The draft Bill and Policy would not have appeared to have taken into account the important implications on access to medicines and broader developmental concerns. Similarly, it is not clear that the policy and draft Bill were developed on the basis of empirical evidence taking into consideration relevant economic data. It remains to be seen whether the draft Bill and Policy will be adopted in their current state or whether further research to determine the impact of the draft Bill and Policy on access to medicines among other things, will be conducted.

2.7 Conclusion

In re-tracing the development of international intellectual property norms from their origins in the nineteenth century to the present day “TRIPS plus era” this chapter has found that the ratcheting up of intellectual property protection and enforcement standards is an agenda being driven by industrialized countries who were and continue to be the largest beneficiaries of stronger intellectual property standards. This chapter also notes that, while safeguards and flexibilities were incorporated into the TRIPS Agreement to provide a balance between incentivizing innovation on the one hand and the dissemination of the benefits of innovation on the other, attempts by developing countries to utilize these flexibilities and safeguards in the TRIPS Agreement to increase access to essential medicines were opposed by developed countries, particularly the US resulting in a number of these disputes being brought before the dispute settlement mechanism of the WTO.

The chapter raises questions over the effectiveness of the mechanism created by the 30 August 2003 Decision authorising the compulsory licensing and export of pharmaceutical technologies to supply patients in countries with insufficient manufacturing capacity. The chapter finds that the first hypothesis advanced in chapter one, namely, that the incorporation and use of public health related TRIPS flexibilities has not been needed to treat patients in eastern and southern African countries is supported by the gradual assent of countries in the region to the agreement to amend Article 31 of TRIPS and the large amounts of funding received by countries in the region from the GFATM and PEPFAR programmes.

Finally, by retracing the evolution of intellectual property to the present day, this chapter concludes that the implications of intellectual property protection on public health and access to medicines were not properly understood by eastern and southern African countries during the negotiations leading up to the creation of the TRIPS Agreement and that once the implications became clear with the onset of disputes on intellectual property and public health at the WTO together with the onset of public health crises in the region as discussed in chapter one, the African group of countries participated far more actively in debates on intellectual property at the WTO. Recent developments may result in the implementation of intellectual property enforcement standards which exceed the TRIPS Agreement and possibly jeopardising access to a sustainable supply of medicines in future. While in recent years, a few countries in eastern and southern Africa have attempted to use safeguards and flexibilities to secure a sustainable and affordable supply of essential medicines, the success of these attempts and some of the challenges faced by countries will be discussed in chapter three.

3 Using Public Health Related TRIPS Flexibilities to Increase Treatment Access: Experiences from Eastern and Southern Africa

“To be prepared is half the Victory”

3.1 Introduction

As discussed above in chapter two, countries in eastern and southern Africa had limited involvement in intellectual property norm setting before the launch of the Uruguay trade round in 1986. However, once the implications of the TRIPS Agreement on public health became clearer by the late 1990s, the African Group whose membership comprises several eastern and southern African countries became increasingly involved in debates at the TRIPS Council in a bid to ensure that WTO Members could use public health related flexibilities found therein to address public health concerns.

This chapter examines the extent to which key public health related TRIPS flexibilities have been incorporated into national legislation by countries in the region. Moreover, the chapter will analyse instances where public health related flexibilities were utilized by countries in the region as well as instances where countries threatened or attempted to use public health related TRIPS flexibilities, and what the implications for treatment access were. In so doing, this chapter will test the first two hypotheses advanced in chapter one, namely, that the incorporation of public health related TRIPS flexibilities into national legislation of countries in eastern and southern Africa has not been a priority to date, and that there are capacity constraints within the relevant government departments in the region which explains the partial adoption and integration of public health related flexibilities. The more specific examples examined in this chapter include an analysis of the impact of legislation passed in South Africa to facilitate parallel importation of essential medicines as well as the use of competition law by civil society groups to increase generic competition. In addition, the chapter will also analyse the orders for government use of patented ARVs by authorities in Mozambique and Zambia as well as Rwanda's use of the WTO 30 August 2003 Mechanism. The chapter will also discuss the threat by the government of Kenya to issue a compulsory license in 2004 and the implications of this action on treatment access as a result. In conclusion, the chapter will assess whether the incorporation and use of public health related

TRIPS flexibilities has been successful in decreasing treatment costs, thus increasing access to treatment.

3.2 The Use of Compulsory Licensing and Government use Orders

Compulsory licenses are granted by executive, administrative or judicial authorities to third parties to exploit a patented invention without the consent of the patent holder while government use orders are compulsory licenses for use by government authorities. As observed by Mandich in chapter two, compulsory licensing has existed as a concept since the formal recognition of intellectual property protection, the rationale being that a patent is not an absolute right and can be revoked under certain circumstances. In the international level, compulsory licenses are regulated both by the Paris Convention,¹⁹⁶ and Article 31 of the TRIPS Agreement, with the latter authorizing WTO Members to issue compulsory licenses for a variety of reasons. These include the lowering of high prices of health technologies,¹⁹⁷ to counter anti-competitive practices,¹⁹⁸ a failure or refusal by the patent holder to supply the market with sufficient quantities of health technologies or to meet a need caused by a situation of extreme urgency.¹⁹⁹ It is widely agreed that Article 31 does not provide an exhaustive list of the grounds on which a compulsory license may be issued.²⁰⁰

¹⁹⁶ Article 5A (2) of the Paris Convention notes that:

“Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights” conferred by the patent.”

¹⁹⁷ See for example, Martin G, Sorenson C, and Faunce T, (2007) “Balancing Intellectual monopoly privileges and the need for essential medicines” *Globalization and Health* 3:4, Ford N et al (2007) “Sustaining access to antiretroviral therapy in the less developed world: lessons from Brazil and Thailand” *AIDS* 21 (suppl4): S21-S29, and Nunn A, Fonseca E, Bastos F, Gruskin S, Salomon J (2007) “Evolution of antiretroviral drug costs in Brazil in the context of free and universal access to AIDS treatment.” *PLoS Med* 4(11): e305 [Online] Available:

<http://medicine.plosjournals.org/perlserv/?request=get-document&doi=10.1371/journal.pmed.0040305&ct=1>.

See also, Musungu S, and Oh C, (2005) ‘The use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?’ Study 4C, Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH), at 23 [Online] Available: <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>

¹⁹⁸ See Article 31(k) of TRIPS.

¹⁹⁹ An incident that was regarded to have constituted a situation of extreme urgency was the issuance of a compulsory license in Taiwan in 2005 for the production of tamiflu. The German Press Agency, Deutsche Presse-Agentur quoted the Taiwanese Secretary General of the Department of Health as saying that “Roche and Gilead insisted they can supply enough tamiflu if bird flu erupts in Taiwan. Our argument was: When there is a bird flu pandemic, millions of people will be hospitalized or dead, and some countries might confiscate Tamiflu or ban its export. We cannot gamble our people's lives on their unreliable promise.” See KEI Research Note 2007:2 (1) [Online] Available: <http://keionline.org/content/view/41/1>

²⁰⁰ ICTSD-UNCTAD, (2005) at 462.

Article 31 of TRIPS does however contain a number of conditions to be met for a compulsory license to be issued. For instance, the license applicant is required to have undertaken negotiations or attempted to negotiate terms and conditions with the patent holder for a voluntary licence to be concluded on reasonable terms and conditions without success.²⁰¹ This requirement may be waived in the event of a national emergency, a situation of extreme urgency or other instances where the license is granted for public non-commercial use. However, the TRIPS Agreement requires that the patent holder be informed as soon as practicably possible²⁰² and should be paid “adequate remuneration”,²⁰³ although the remuneration to be paid may be subject to further legal review.²⁰⁴

The requirement in Article 31 that has had the greatest impact on the ability of countries in eastern and southern Africa to issue compulsory licenses is Article 31(f) which requires that compulsory licenses be used to predominantly supply the domestic market.²⁰⁵ As discussed in chapter two, this has had the consequence of limiting the use of Article 31 to countries with a significant domestic pharmaceutical manufacturing base, to the exclusion of countries in the region with the exception of South Africa. There have been instances where Article 31(f) has limited the effective use of compulsory licenses issued by countries in eastern and southern Africa. A brief summary of the instances where countries in the region have either utilised or attempted to use TRIPS flexibilities to advance public health objectives and the outcomes of their actions follows below.

²⁰¹ Article 31(b) which reads:

“such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.” As no guidance is provided by the TRIPS Agreement to determine what constitutes a “reasonable time”, WTO Members retain the discretion to further define this in national legislation or regulations.

²⁰² The relevant portion of Article 31(b) reads as follows:

“In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly.”

²⁰³ According to Article 31(h), WTO Members retain the discretion to define what constitutes adequate remuneration. Several countries have referred either to guidelines developed by UNDP as part of its research into the 2001 Human Development Report, or to a tiered royalty method proposed by James Love. Both methods and approaches by patent offices from a number of jurisdictions including Canada and Japan can be found in Love J, (2005) ‘Remuneration guidelines for non-voluntary use of a patent on medical technologies’, WHO/TCM.1 [Online] Available: http://www.who.int/medicines/areas/technical_cooperation/WHOTCM2005.1_OMS.pdf

The Canadian Access to Medicines Regime (CAMR), enacted to give effect to the August 30 2003 Decision has a similar scale used to determine compulsory licensing royalties based on a country’s ranking on the UNDP’s Human Development Index (HDI).

²⁰⁴ Article 31 (i).

²⁰⁵ Article 31(f).

3.2.1 Zimbabwe's Government Use Order

As an integral member of the African Group at the WTO, Zimbabwe became the first sub-Saharan African country to use Article 31 of the TRIPS Agreement in a bid to reduce the costs of ART. Shortly after the Doha Declaration on TRIPS and Public Health was concluded in November 2001, Zimbabwe amended its Patents Act²⁰⁶ to further incorporate public health related TRIPS flexibilities and inserted two key amendments regulating compulsory licensing and government use. Section 34 was amended to authorize the Minister of Justice, Legal and Parliamentary Affairs to permit in writing, any department of the state or person to:

“Make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section”.

The broad wording of Section 34 authorized the government to issue a compulsory license without requiring negotiations with the patent holder as envisaged by Article 31(b) of the TRIPS Agreement. Section 35 enabled the Minister to give a third party or person:

*“The powers to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient”.*²⁰⁷

To give effect to Section 35, in May 2002, government authorities in Zimbabwe issued a Declaration of Emergency²⁰⁸ valid for six months. It is reported that the declaration of emergency

²⁰⁶ Statutory instrument 128 of 1996.

²⁰⁷ Section 35 authorizes the non-voluntary use of a patented invention:

*“(a) for the efficient prosecution of any war in which Zimbabwe may be engaged; or
(b) for the maintenance of supplies and services essential to the life of the community; or
(c) for securing a sufficiency of supplies and services essential to the well-being of the community; or
(d) for promoting the productivity of industry, commerce or agriculture; or
(e) for fostering and directing exports and reducing imports or imports of any classes, from all or any countries and for redressing the balance of trade; or
(f) generally, for ensuring that the whole resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or
(g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any part of Zimbabwe or any foreign country that is in grave distress as the result of war”;*

²⁰⁸ The Declaration of Period of Emergency (HIV/AIDS) Government Notice 240 of 2002.

was only for six months because of concerns by the Ministry of Health that it could be challenged by originator pharmaceutical companies. Once it became clear that this was unlikely to occur, the Minister of Justice extended the period of emergency from 1 January 2003 to 31 December 2008.²⁰⁹ This presented the government with the opportunity, either to import generic versions of ARVs under patent in Zimbabwe, or to authorize the local production of generic equivalents. In April 2003, the Minister of Justice, Legal and Parliamentary Affairs wrote a letter to a local pharmaceutical manufacturer Varichem authorising it to manufacture ARVs for the supply of the local market and to supply 75 percent of its medicines to state run health institutions.²¹⁰ From its initial production of zidovudine and lamivudine in July 2003, Varichem went on to produce a number of first line ARVs including stavudine and nevirapine. Before Varichem had begun producing ARVs, it was reported that the cost of ART per patient per year varied between US\$ 360 to US\$ 600. By contrast, the combination of stavudine, lamivudine and nevirapine was being sold in October 2003 at US\$ 12.80 for 60 tablets, which amounted to a month's supply²¹¹ or as little as US\$153.60 per patient per year.²¹² Without WHO pre-qualification or approval by the US FDA, local manufacturers remain ineligible to participate in treatment programs financed by the GFATM and PEPFAR which, as discussed in chapter one, impeded their ability to generate sufficient orders required to manufacture medicines cost effectively.

In October 2010, Varichem obtained WHO pre-qualification for the ARVs it was producing, becoming only the fourth pharmaceutical company in Africa to have done so.²¹³ In 2012, news stories emerged that Varichem had stopped producing ARVs because of it was not receiving any orders from health authorities in Zimbabwe.²¹⁴ According to officials from the company, Varichem was not receiving any orders from the public sector as the large majority of medicines procured

²⁰⁹ According to a report from a Zimbabwean newspaper the Herald dated 20 January 2003 as reported by the United States Centre for Disease Control (CDC) New Brief of January 23 2003:

<http://www.thebody.com/content/art28934.html>

See also, Musungu and Oh (2005)

²¹⁰ Osewe P, Nkrumah Y, and Sackey E, (2008) 'Improving Access to HIV/AIDS Medicines in Africa: Trade-related Aspects of Intellectual Property Rights Flexibilities', World Bank, Washington DC.

²¹¹ Ibid Osewe et al at 31.

²¹² Musungu and Oh at 23, note that Varichem agreed to produce a combivir, a combination of zidovudine and lamivudine US\$15 a month, or US\$ 180 per patient per year.

²¹³ After Aspen Pharmacare and Sandoz in South Africa and Quality Chemicals in Uganda.

²¹⁴ See News Article from the Zimbabwe Herald of 7 March 2012 *Varichem Stops Producing ARVs* [Online] Available: <http://www.essentialdrugs.org/edrug/archive/201203/msg00056.php>

for public sector use were donor funded, and that donors did not procure locally manufactured medicines. This case serves as a stark reminder of how wholly donor funded treatment programmes may contribute to the decline of local pharmaceutical manufacturing industries, contrary to the desired outcomes of the policies being adopted at the sub-regional and regional levels to develop local pharmaceutical production capacity as discussed further in chapter six below.

3.2.2 Compulsory licenses in Mozambique and Zambia in 2004

If the government use order by Zimbabwean authorities is regarded as a successful example of how treatment costs were reduced through the use of public health related TRIPS flexibilities, then the compulsory licenses issued by government authorities in Mozambique and Zambia serve as a stark reminder of the challenges and complexities countries in the region can face when issuing compulsory licenses. Mozambique was the first of the two countries to act, issuing a compulsory license²¹⁵ for the local production of a first line ART combination containing zidovudine, lamivudine and nevirapine in April 2004. The license was issued by the Deputy Minister of Industry and Commerce²¹⁶ and was the result of a proposal²¹⁷ by a generic pharmaceutical manufacturer, Pharco Ltd²¹⁸ to manufacture a cost-effective first line ART regimen. In September 2004, the Zambian Minister of Domestic Trade and Consumer Affairs followed suit, issuing a compulsory license²¹⁹ for the same first line combination ART, to be manufactured in Zambia by a locally incorporated version of Pharco Ltd.²²⁰

²¹⁵ Compulsory License no. 01/MIC/04. See Love J, (2008) 'Recent examples of the use of compulsory licenses on patents' KEI Research Note 2, [Online] Available: http://keionline.org/misc-docs/recent_cls_8mar07.pdf . See

²¹⁶ An unofficial translated version of the license [Online] Available at:

<http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>

²¹⁷ This is according to a comment by James Love on 19 May 2004 on the list-serve e-drug. His full comments, which also assert that the license was effective from 29 March rather than 5 April are [Online] Available at:

<http://www.essentialdrugs.org/edrug/archive/200405/msg00031.php>

²¹⁸ Pharco pharmaceuticals is an Egyptian generic pharmaceutical company established in 1987. Since then, the holding company Pharco Corporation has become the largest Egyptian pharmaceutical company with a workforce exceeding 5 700 employees with exports to 57 countries.

²¹⁹ Compulsory License No. CL 01/2004.

²²⁰ The text of the Zambian compulsory license is [Online] Available at:

<http://www.cptech.org/ip/health/c/zambia/zcl.html>. The two licenses are almost identically worded with the significant difference being the royalty rates of remuneration. For the compulsory license issued by the government of Mozambique, royalty was established at 2 percent of turnover, which the Zambian compulsory license set a rate of 2.5 percent.

Despite the issuance of compulsory licenses for the local production of the same medicine in both countries, and despite having presented a project proposal of how the ARVs were to be manufactured locally, no production of ARVs ever took place by Pharco. Various reasons have been advanced for this. It has been asserted by some, that the only way that Pharco Ltd was going to be able to offer a competitive price for the product in question, was to achieve an economy of scale by obtaining pre-qualification by the WHO, thus making it eligible for to compete for Global Fund financed procurement contracts. Once it became clear that this was unlikely to happen,²²¹ the endeavour to produce locally manufactured ARVs in both countries stalled. It later transpired that the medicines that were the subject of the compulsory licenses in Mozambique and Zambia were not actually patented in Zambia, while their patent status in Mozambique was unclear.²²²

As compulsory licenses are issued only where valid patents exist, there was actually no need for a compulsory license to have been issued in Zambia at all. In the case of Mozambique, a thorough search of the patent status for the three ARVs in question should have taken place to establish whether there were indeed valid patents in force, and whether it was necessary to issue a compulsory license to authorise generic production of the said medicines, or whether the absence of valid patents meant that generic production could have taken place without the issuance of a compulsory license.

The compulsory licensing examples from Zambia and Mozambique illustrate some of the capacity constraints facing countries in the region in using public health related TRIPS flexibilities. It was not clear that there were valid patents on any of the three ARVs in question in either country and whether as a result, there was a need to issue compulsory licenses to facilitate local manufacturing.

²²¹A report by the Forum for African Investigative Reporters (FAIR) entitled ‘The Indifferent Pharmaceutical Industry: Big Pharma, essential medicines and Africa’s sick’ (2008) is [Online] Available: http://www.fairreporters.org/portal/pdf/FAIR_proof_4.pdf, alleges that in the case of Zambia, Pharco Ltd was named as the local producer of ARVs because it the government was a shareholder in the company and that a conflict of interest prevented the government from appearing to promote a company it had a direct interest in, at the expense of being able to purchase more affordable ARVs from foreign generic manufacturers.

²²² According to an official from the then titled Patents and Companies Registration Office (PACRO) of Zambia. It remains unclear whether the medicines were ever patented in Mozambique although a search of the MPP patent database shows that while patents applications were filed and granted by ARIPO for several forms and combinations of lamivudine, zidovudine and nevirapine. There is no indication of whether patent authorities in Mozambique chose to not recognize these patents as is their prerogative under the Harare Protocol.

In most patent offices in eastern and southern Africa, it can be difficult to obtain access to accurate and current information on what patent applications have been filed and, if granted, whether they are being maintained. While Zambia has a local patent office with modest but increasing capacity to examine patent applications, Member States of ARIPO including Mozambique and Zambia mostly rely on the ARIPO Secretariat's patent examiners²²³ to substantively examine pharmaceutical patent applications. While patent examiners employed by ARIPO conduct substantive patent examinations on behalf of Member States, and in some instances, the observer countries,²²⁴ each Member State has a six month period from the granting of a patent by an ARIPO patent examiner to confirm or reject the application of the patent in its territory.

There has been at least one instance where a patent was granted by an ARIPO patent without notification reaching a Member State due to difficulties in communication, thus resulting in the grant of a patent in an ARIPO Member State without the approval of the national patent office in question.²²⁵ Aside from the complexities that ARIPO membership may bring with it, the ability to check the validity of patents in countries like Mozambique and Zambia can be challenging. Obtaining accurate and up to date information in many developing countries is often difficult, due to the fact that patent offices in many African countries do not have electronic patent databases, which necessitates a manual patent search.²²⁶

The absence of accurate and updated information on the patent status of key ARVs has, to some degree, been alleviated by availability of patent information through the online patent database maintained by the Medicines Patent Pool (MPP), which provides periodical information on the patent status of key ARVs as verified by national and regional offices. However, this information

²²³ The Member States of ARIPO are: Botswana, Gambia, Ghana, Kenya, Lesotho, Liberia, Malawi, Mozambique, Namibia, Rwanda, São Tomé and Príncipe, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe.

²²⁴ In addition to the 19 Member States, there are 12 observer countries which are regarded as potential ARIPO members. These are: Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Libya, Mauritius, Nigeria, Seychelles, South Africa and Tunisia.

²²⁵ This was disclosed by a participant who prefers to remain unquoted at a meeting organized by UNDP, WHO and the University of Cape Town on the examination of pharmaceutical patents from a public health perspective in Cape Town in October 2008.

²²⁶ For a lengthier discussion of some of the challenges facing developing country patent offices, see WHO (2004) 'Determining the patent status of essential medicines in developing countries' Health Economics and Drugs, EDM series No.17.

is only periodically updated. Information on the MPP database pertaining to ARIPO was last updated in November 2013. The inability to obtain timely, accurate and up to date information on the patent status of key ARVs supports the second hypothesis advanced in chapter one regarding the capacity constraints facing countries in eastern and southern Africa in utilizing TRIPS flexibilities.

Another aspect related to the capacity constraints facing countries in eastern and southern Africa is the failure of the relevant authorities to fully incorporate public health related TRIPS flexibilities into domestic patent legislation. As discussed by Matthews,²²⁷ developing countries in some instances may have simply lacked the requisite institutional capacity to effectively incorporate and use flexibilities effectively. This challenge would have been compounded by the provision of insufficient or inappropriate technical assistance from developed country and multilateral donors in some cases.²²⁸

3.2.3 An effective compulsory licensing threat in Kenya

With the passing of an Industrial Property Act in 2001²²⁹ enacted to comply with its obligations under the TRIPS Agreement, Kenya incorporated key public health related TRIPS flexibilities into its domestic legislation including revised provisions on compulsory licensing. In addition to the new Industrial Property Law, the Kenyan government's National Drug Policy²³⁰ remained supportive of the domestic pharmaceutical industry, easily the largest in the EAC comprising of up to 40 local pharmaceutical manufacturers.²³¹ Between 1995 and 2003, up to six Kenyan generic manufacturers had attempted to negotiate voluntary licenses with the originator companies GlaxoSmithKline (GSK) and Boehringer Ingelheim to locally manufacture the first line ARVs

²²⁷ Matthews D, (2005) 'TRIPs Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements' EIPR Issue 11, 420-427.

²²⁸ Ibid Matthews at 427.

²²⁹ Industrial property Act 3 of 2001.

²³⁰ The Policy which was adopted in 1994, recommends the granting of duty remissions for manufacturers and requires that intellectual property rules strike a balance between promoting local manufacturing and protecting consumers from excessive prices. [Online] Available: <http://apps.who.int/medicinedocs/documents/s16443e/s16443e.pdf>

²³¹ UNIDO (2010) 'Pharmaceutical Sector Profile: Kenya' [Online] Available: http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Kenya_Pharma%20Sector%20profile_TEGLO0501_5_Ebook.pdf

zidovudine, lamivudine and nevirapine. However, the terms and conditions offered by both companies would have made local manufacturing impracticable.²³² Shortly after the 30 August 2003 Agreement was concluded, the Kenyan generic manufacturer Cosmos Pharmaceuticals announced its intention to begin producing generic versions of the first line ARVs for the east African market after winning a government tender to do so.²³³ This development prompted additional negotiations between Cosmos and GSK²³⁴ resulting in a licensing agreement in September 2004 between the two companies for the local production of zidovudine, lamivudine and the combination of the two, combivir by Cosmos.²³⁵

Two developments hampered the production of the ARVs by Cosmos. First, it had only been able to negotiate a voluntary license to supply the five EAC Partner States.²³⁶ It was unclear whether this was a sufficiently large market at the time for local production to be cost effective. Second, after concluding the voluntary license with Cosmos, GSK subsequently reduced its prices for the ARVs in the Kenyan market, to make local production by Cosmos economically unviable. While predatory pricing is recognised in many countries as anti-competitive behaviour,²³⁷ it went unchallenged by Cosmos, possibly because it did not constitute a ground for anti-competitive behaviour under applicable legislation in Kenya. While this was an unfortunate result for Cosmos,

²³² Osewe et al at 33.

²³³ According to a BBC news report on 22 September 2004 *Kenyan Firm to Make AIDS Drugs* [Online] Available: <http://news.bbc.co.uk/2/hi/africa/3680672.stm>

²³⁴ According to reports from the Kenyan Newspaper the Daily Nation dated 22 September 2004, the Ministry of Health ordered that generic drugs be produced while the Ministry of Trade and Industry under whose ambit the 2001 was administered, refused to issue a compulsory licence. An electronic version of the story is available on the listserv Essential drugs at: <http://www.essentialdrugs.org/edrug/archive/200409/msg00027.php>

²³⁵ Ibid. It is not clear whether Boehringer Ingelheim was approached by any domestic manufacturers to negotiate a voluntary licence. However in 2007, the company declared that it would not seek to enforce any of its patents for nevirapine in 70 countries around the world including those classified by the World Bank as Low Income Countries (LICs), those classified by the UN as LDCs, and all countries in Africa regardless of their classification as a developing country, or Middle Income Country. The policy was extended to a second line ARV tipranavir, for which Bayer is also the patent holder. An electronic version of the policy is [Online] Available: http://corporateresponsibility.boehringeringelheim.com/content/dam/internet/opu/com_EN/document/01_news/05_Media_Material/policy_paper_on_hiv_aids.pdf

²³⁶ Burundi, Kenya, Rwanda, Tanzania and Uganda. See Shiya (2005) 'Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya' in *Managing the Challenges of WTO Participation - 45 Case Studies*, Cambridge University Press [Online] Available: http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm#fnt41

²³⁷ See for example, Maskus K, and Lahouel M, (2000), Competition Policy and Intellectual Property Rights in Developing Countries. *World Economy*, 23: 595–611 for a discussion on predatory pricing. See also Abbott F, (2014) 'Anti-Competitive Behaviours and the Remedies Available for Redress' in UNDP, *Using Competition Law to Promote Access to Health Technologies: A guidebook for low- and middle-income countries* 58-95

the consumers appeared to have benefitted from lower ARV prices²³⁸ at least in the short term. Cosmos has not successfully completed the WHO's prequalification program thus making it eligible to receive Global Fund funding. The company, while producing several types of first line ARVs has not become a large regional supplier. From the perspective of increasing treatment access, this case is an illustration of how the adoption and potential use of public health related TRIPS flexibilities can lead to reduced treatment costs even if it may not always result in increased local pharmaceutical production.

3.2.4 The WHO-UNICEF “Paragraph 7” Model Letters

As discussed in chapter two, the Doha Declaration, while re-affirming the rights of WTO Members to use key public health related TRIPS flexibilities, did not resolve the multiple challenges facing countries who attempted to use them. The ARIPO system of notifying Member States of decisions it reached after undertaking substantive patent examinations has created an environment where some of its Member States cannot always be certain of the patent status of key ARVs in their countries. Second, ARV procurement is a function which at the national level, occurs within the ministry of Health. Ministry of Health officials are even less likely to have current information on the patent status of ARVs they may be importing. A number of organisations involved in the procurement of ARVs became wary of the potential risk involved in importing ARVs whose patent status could not be verified. In a bid to mitigate this risk, the IDA Foundation²³⁹ which at the time was a large procurer of ARVs in Africa, developed a letter summarizing the various scenarios facing developing countries and LDCs. The letter²⁴⁰ requires that one of the following documents be supplied by importing countries before shipment would take place:

²³⁸ Avafia T, Berger J, and Hartzenberg T (2006) ‘The ability of select sub-Saharan African countries to utilise TRIPS Flexibilities and Competition Law to ensure a sustainable supply of essential medicines: A study of producing and importing countries.’ Tralac Working Paper No 12. Stellenbosch.

²³⁹ The IDA Foundation is a not for profit organization established in 1972 by a small group of pharmacists and now supplies more than 3 000 different medicines and medical supplies to over 100 countries worldwide.

²⁴⁰ See “Legal Possibilities to import Generic ARVs and OIs.” [Online] Available: http://www.who.int/hiv/amds/Legal_importinggenericARVs.pdf. The letter erroneously refers to Zimbabwe as an LDC.

- A written statement from the local authorities (e.g. the Minister of Health) that none of the required generic drugs or active pharmaceutical ingredients are under patent in the importing country or;
- A written statement from the local authorities of the importing country that they declare an emergency situation and/or authorize a government use license.

The letter from the IDA Foundation was problematic for a number of reasons. First, it placed an obligation on the Ministry of Health rather than the government office responsible for the administration and management of intellectual property to determine the patent status of key medicines, which, as discussed above in chapter two, is a TRIPS-plus measure. Second, the letter narrowed the scope of the Doha Declaration by requiring that a declaration of emergency be issued by a local authority, in contravention of Paragraph 5(b) of the Doha Declaration which re-affirms the freedom of WTO Members to determine the grounds under which they grant compulsory licenses. A third problem was the mistaken assumption in the letter that a sufficiently large number of patents were being filed, granted and maintained in sub-Saharan African countries to warrant the issuing a government use order as a precautionary or defensive measure. The letter from the IDA Foundation contradicted existing evidence regarding the number of patents that had been filed and granted in sub-Saharan African countries at the time.²⁴¹

In response to the IDA Foundation letter, a number of countries in sub-Saharan Africa wrote letters ordering the government use of generic medicines.²⁴² The legal status of these letters as compulsory licenses or government use orders remains unclear. There is also little evidence indicating that significant cost savings were achieved by importing generic ARVs through IDA as

²⁴¹ See for instance, a report entitled 'Patent Protection and Access to HIV/AIDS Pharmaceuticals' prepared for the WIPO Secretariat by the International Intellectual Property Institute (IIPI) in 2000, which revealed a negligible level of patenting of ARVs in the large majority of sub-Saharan African countries.

²⁴² As most of these letters are direct correspondences between the relevant ministries of health and the IDA Foundation and therefore not available in the public domain, it is unclear how many governments wrote these letters. A letter written by the Ministry of Health in Lesotho to the IDA foundation dated 2 August 2004 is available online at: https://www.who.int/hiv/amds/IP_rightsBRT.pdf. Identical letters drafted by the Minister of Health Eritrea and the Ghanaian Minister of health available online at: <http://www.cptech.org/ip/health/cl/Eritrea.png> and at <http://www.cptech.org/ip/health/cl/Ghana.png>

opposed to sourcing the medicines from for example, local pharmaceutical producers²⁴³ although the latter were often not WHO pre-qualified.

3.3 Parallel importation

In order to counterbalance the practice of differential pricing by originator pharmaceutical companies,²⁴⁴ the TRIPS Agreement enables WTO Members to parallel import medicines from countries where an originator company may have chosen to market the product at a more competitive price. Parallel importation as a concept relies on the principle of exhaustion of rights, or the point at which the patent holder's control over an invention placed on the market ceases. This termination of control is critical to the functioning of any market economy because it permits the free transfer of goods and services. Without an exhaustion doctrine, the original right holder could exercise control over the sale, transfer or use of a good or service for the duration of the patent term.²⁴⁵ The TRIPS Agreement affords WTO Members the discretion to elect a system that recognises national, regional or international exhaustion of rights.²⁴⁶ If a country recognizes a doctrine of "national" exhaustion, a patent holder's right to control movement of a good or service is only extinguished by the first sale or marketing of a good or service within the territory of that country. If a country recognizes a doctrine of "regional" exhaustion, a patent holder's right to control movement is extinguished when a good or service is first sold or marketed in any country of the region, thus allowing importation from the most affordable regional source. If a country recognizes a doctrine of "international exhaustion", a patent holder's right to control movement is extinguished when a good or service is first sold or marketed anywhere in the world,²⁴⁷ thus

²⁴³ Ibid Osewe et al at 44 where a graph indicates that in the case of Ghana, the cost differential between ARVs locally manufactured by Ghanaian generic manufacturer Danadams, and those imported by the IDA Foundation was negligible for lamivudine. There were however, significant cost savings for nevirapine.

²⁴⁴ See Moon et al (2011) 'A win-win solution?: A critical analysis of tiered pricing to improve access to medicines in developing countries' *Globalization and Health*, 7:39 [Online] Available: <http://www.globalizationandhealth.com/content/7/1/39>

²⁴⁵ UNCTAD-ICTSD, (2005) at 93.

²⁴⁶ See Matthews D, and Munoz-Tellez, V (2007) 'Parallel Trade: A User's Guide' In "Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices" (eds). Krattiger A, Mahoney R, Nelsen L, et al.). MIHR: Oxford, UK for An extensive discussion of the concept of parallel importation and the three doctrines of exhaustion. The authors conclude that developing countries should retain as much policy space as afforded by the TRIPS Agreement by incorporating the principle of international exhaustion of rights into national legislation.

²⁴⁷ According to Article 6 of the TRIPS Agreement:

allowing importation from the most affordable global source where the patented product is being sold.

3.3.1 The Dispute over Parallel Importation in South Africa

The international impact of the South African government's decision to pass the Medicines and Related Substances Act²⁴⁸ has been discussed above in Chapter two. The purportedly broad phrasing of Section 15 (C) authorized a minister of state to "*prescribe conditions for the supply of more affordable medicines in certain circumstances*" was interpreted by several originator pharmaceutical companies as an enabling clause for the Minister of Health to issue compulsory licenses and to authorize parallel importation where necessary. Because the South African government had, through existing common law, recognized the international exhaustion of rights and since there was no indication that the parliament intended to change this rule when it amended the Patent Act to implement TRIPS, it is unlikely that Section 15C of the Medicines Amendment Act broke new ground, except perhaps to provide regulatory authority to the Health Minister.²⁴⁹ Initially, the USTR threatened to impose unilateral trade sanctions in retaliation against the South African government, a threat which was withdrawn once the full impact of the public relations implications of the Court case became clear.²⁵⁰

For reasons noted above in chapter two, The US government elected to not initiate WTO Dispute Settlement proceedings and eventually withdrew support for the Court case in South Africa. Nonetheless, the US had placed South Africa on its 301 Special Watch List and employed persistent diplomatic pressure to urge repeal of the Act. Because of growing criticism, the US

"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights."

²⁴⁸ Act 90 of 1997. This Act outlines mechanisms for the Medicines Control Council to regulate the quality, safety, and efficacy of medicines in the country. The amendments that took place included the acceptance of the WHO's Essential Drugs List

²⁴⁹ Ibid UNCTAD-ICTSD (2005) at 111. See also Wilson K, (2009) 'A Manufactured Solution? The Technology Transfer to Developing countries for the Local Production of Affordable Antiretrovirals: Case Studies From Tanzania and South Africa' Doctoral Thesis, Faculty of Pharmacy, University of Toronto from 174-179 for a detailed discussion of the Medicines and Related Substance Act as well and the Court case [Online] Available: https://tspace.library.utoronto.ca/bitstream/1807/17841/1/Wilson_Kinsley_R_200906_PhD_Thesis.pdf

²⁵⁰ Wilson at 176. Several international NGOs including Act Up, MSF, Oxfam, Health Gap as well as political leaders like Nelson Mandela heavily criticized the pharmaceutical industry for charging excessive prices for medicines. MSF also launched a campaign entitled "drop the case which led to more than 300 000 people signing a global petition.

recanted this pressure, and President Clinton adopted an Executive Order preventing the USTR from interfering with African countries TRIPS-compliant efforts to ensure access to AIDS medicines.²⁵¹ The South African government maintained during the course of the Court case that Section 15(C) was only ever going to be used for parallel importation, and claimed victory once the case was dropped. Some question whether the South African government could claim victory given its narrow interpretation of the Act and the fact that to date, Section 15(C) has not been used to parallel import medicines.²⁵² As will be elaborated upon in chapter five, the South African Department of Health has negotiated some of the lowest ARV prices in the world and if follows from this that the need has not arisen for the government to use Section 15(C). However, as will also be discussed in chapter five, the cost of new and emerging health technologies required to treat HIV and co-infections such as TB and hepatitis as well as NCDs like cancer may eventually require the South African government to make use of Section 15(C) and other flexibilities present in patent, medicines and competition legislation.

3.3.2 Kenya's interpretation of Parallel Importation

As noted earlier, the passing of an Industrial Property Act in 2001 afforded the Kenyan government the opportunity to provide for parallel importation, a flexibility that was not available under its previous intellectual property legislation with the result that Kenya had become a segmented market controlled by patent holders.²⁵³ In addition to Section 58 of the 2001 Industrial Property Act²⁵⁴ which provides for the international exhaustion of rights, Clause 37 of Kenya's Intellectual Property Regulations²⁵⁵ elaborates on Section 58 by noting that it applies to:

²⁵¹ Executive Order 13155.

²⁵² Hassim A, Heywood M, and Berger J, (2007) *Health and democracy: A guide to human rights, health law and policy in post-apartheid South Africa.* Siber Ink, Cape Town.

²⁵³ Nyaga J, (2009) 'Implementing Parallel Importation and Licensing Mechanisms to Increase Access to Medicines in Kenya', Master's Thesis, Stanford Law School at 41, [Online] Available:

http://www.law.stanford.edu/publications/dissertations_theses/diss/JacklineNyaga-tft2009.pdf

See also Lettington R, and Munyi P, (2004) 'The Willingness and Ability to use TRIPS Flexibilities: Kenya Case Study' Access to Medicines Issues Paper, DFID Health Systems and Resource Centre [Online] Available: <http://www.dfidhealthrc.org/publications/atm/Lettington2.pdf>

²⁵⁴ Section 58(2) notes that:

"The rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya."

²⁵⁵ The Minister of Trade, is authorized under Section 119 of the Industrial Property Act, to create regulations as necessary to further implement the Act. In 2002, the Minister passed drafted regulations to complement Section 58 of the Industrial Property Act.

“...articles that are imported from a country where the articles were legitimately put on the market”.

The wording of the regulation subsequently permits the importation of a medicine placed on the market by a generic company in the event that no domestic patent protection existed. It has therefore been argued that the provision also applies to medicines produced, for example, under a compulsory license, as the recipient of the compulsory license would have been authorized by government authorities to use the invention. Since Kenya’s change of legislation, the provision has been used to import a range of generics that were still under patent protection in the country.²⁵⁶ Until now, there has not been an incident to prompt the challenging of this interpretation of international exhaustion of rights. The High Court of Kenya, in a recent ruling chose not to address the issue of parallel importation in a case that was largely concerned with trademark infringement although one of the parties had alleged a right to import generic medicines manufactured in India on the basis of Section 58 of the Industrial Property Act.²⁵⁷

3.4 Competition Law as a Public Health Related TRIPS Flexibility

Competition law remains one of the least discussed and used public health related TRIPS flexibilities despite the fact that certain flexibilities may enable government officials to circumvent some of the administrative requirements found in Article 31 of TRIPS.²⁵⁸ Other relevant provisions in the TRIPS Agreement relating to competition include Article 6, the more generally applicable Article 8, authorizing countries to take appropriate measures to prevent the abuse of right by patent

²⁵⁶ Ibid Shiya at 41.

²⁵⁷ In the case of *Lords Healthcare Limited v Salama Pharmaceuticals Limited* (2008) Kenyan Law Reports, the plaintiff, a locally registered importer and distributor of generic pharmaceuticals has successfully won a tender from state hospitals to supply an asthma inhaler manufactured in India by generic company Cipla. The plaintiff registered a trademark for the product in Kenya and successfully won a few tenders from state hospitals. Upon failing to win a tender, the plaintiff discovered that the defendant, a competing distributor, had been selling the same product, under the plaintiff’s same trademark. Upon being sued for trademark infringement, the defendant countered that its actions were permissible under parallel importation provisions of the Industrial property Act. The Court dismissed the application of the plaintiff company without addressing the substance of the defendant’s contention.

²⁵⁸ Article 31(k) of the TRIPS Agreement waives the restriction under Article 31(b) of TRIPS that pharmaceutical products manufactured a compulsory license must be predominantly for domestic use. Unlike compulsory licenses issued under Articles 31 (b) and (f), compulsory licenses granted as a remedy for anti-competitive behaviour require no prior negotiations with the patent holder.

holders²⁵⁹ and the more specific Article 40 which authorizes WTO Members to regulate the restrictive practices that may be employed by patent holders to stifle competition.²⁶⁰ While intellectual property provides the patent holder with exclusive rights to control and manage an intellectual asset, competition law seeks to avoid market barriers and benefit consumers by encouraging competition among a multiplicity of suppliers of goods, services and technologies. Dealing with such a relationship may pose challenges for policymakers.²⁶¹

The issue of treatment access highlights the importance of focusing on complementary linkages between competition law and policy on the one hand and intellectual property law on the other. The fact that both can be employed to increase access to various commodities, stimulate innovation, enhance consumer welfare and prohibit actions that could harm the consumers' interest are increasingly recognized.²⁶² While competition laws in most developing countries are relatively new, the number of countries that have passed legislation between the 1990s and 2000 number are 50 in number with the majority being developing countries.²⁶³ The scope and extent to which intellectual property issues are addressed by competition legislation remains at the discretion WTO Members. A strong indication of the 'standardizing' of competition policy and legislation in recent years has been the development of the UN Set of Principles on Competition which recognize the development dimension of competition law and policy, provide rules for the control of anti-competitive practices and a framework for international operation and exchange of best

²⁵⁹ Which provides that:

"Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology."

²⁶⁰ Keeling D, (2003). *Intellectual Property Rights in the EU Law: Free Movement and Competition Law, Volume 1*, Oxford University Press. Oxford.

²⁶¹ Kovacic W, and Reindl A, (2005) 'An Interdisciplinary Approach to Improving Competition Policy and Intellectual Property Policy' *Fordham International Law Journal* 28:1062-1090. For a more detailed discussion of competition related TRIPS flexibilities, see Correa C, (2014) in UNDP, "Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries", United Nations Development Program, New York.

²⁶² Antitrust Guidelines for the Licensing of Intellectual Property, issued by the US Department of Justice and Federal Trade Commission, April 6, 1995, §1.0, [Online] Available:

www.usdoj.gov/atr/public/guidelines/0558.pdf

²⁶³ Correa C, (2007) 'Intellectual Property and Competition Law: Exploring some Issues of Relevance to Developing Countries' *International Centre for Trade and Sustainable Development, Issue Paper 21* at 1. See Flynn S, (2008), 'Using Competition Law to Promote Access to Medicines', *Program on Information Justice and Intellectual Property* [Online] Available:

http://www.ggp.up.ac.za/human_rights_access_to_medicines/syllabus/2009/day3/3FlynnUsingCompetitionLawtoPromoteAccessToMedicin.pdf

practices.²⁶⁴ However, the likelihood of a multilateral competition agreement under the framework of the WTO has decreased in recent years after the WTO Singapore Ministerial²⁶⁵ in 1996 resulted in the creation of a Working Group in 1997 to further examine the linkages between competition policy and trade, because, in part, of reservations²⁶⁶ about the benefits of such an agreement for developing countries, and an attempt by WTO Members to narrow the issues subject to negotiation to increase the likelihood of completing of the Doha Round. The ‘July Package’ adopted by the WTO General Council in August 2004 agreed that competition issues:

*“will not form part of the Work Programme set out in that Declaration and therefore no work towards negotiations on any of these issues will take place within the WTO during the Doha Round.”*²⁶⁷

The absence of progress in agreeing to a multilateral agreement on competition does not prevent individual members from using relevant provisions in the TRIPS Agreement to increase access to health technologies. Government authorities in South Africa for instance, have passed a competition Act for a range of purposes, including the promotion of “the efficiency, adaptability and development of the economy” and the advancement of social and economic welfare.²⁶⁸

3.4.1 Using Competition Law in South Africa to Reduce the Cost of Treatment

The use of competition law by treatment activists in South Africa can be attributed to various factors. These include a progressive constitutional framework,²⁶⁹ a competition Act endowed with

²⁶⁴ See UNCTAD (2001), The United Nations Set of Principles on Competition, Geneva [Online] Available: <http://www.unctad.org/en/docs/tdrbpconf10r2.en.pdf>

²⁶⁵ See Paragraph 20 of the Singapore Ministerial Declaration at WT/MIN(96)/DEC

²⁶⁶ According to Hoekman B, and Mavroidis P, (2002) ‘Economic Development, Competition and the WTO’, World Bank Policy Research Working Paper 2917, Washington DC [Online] Available: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=636279

An agreement along the lines proposed by WTO Members will create compliance costs for developing countries while not addressing the anticompetitive behaviour of firms located in foreign jurisdictions.

²⁶⁷ Paragraph 1(g) the Decision Adopted by the WTO General Council on 2 August 2004 at, WT/L/579.

²⁶⁸ Sections 2(a) and (c) of the Competition Act, 89 of 1998.

²⁶⁹ In the case of *Minister of Health and Others v. Treatment Action Campaign and Others*, 2002 (5) SA 721 (CC), available at: <http://www.constitutionalcourt.org.za/site/thecourt/history.htm#cases>, The Court held that sections 27(1) and (2) of the Constitution require the government to implement a program to combat mother-to-child transmission of HIV.

several enabling provisions,²⁷⁰ a vibrant and assertive civil society with comparatively strong legal resources, who, as discussed in detail by Mathews,²⁷¹ were able to effectively frame debates about intellectual property and competition law under the Bill of rights which included a constitutional right to health.²⁷² The factors also include a Competition Commission with the institutional capacity to enforce a progressive Act, and the political will of its officials to tackle complaints related to health-care in general.²⁷³

Motivated by a need to increase the levels of HIV treatment in the early 2000s, activists began to use competition law as a tactic to stimulate generic competition in ARVs.²⁷⁴ Acting under section 49(2) (b) of the Competition Act, which permits ‘any person’ to ‘submit a complaint against an alleged prohibited practice’, complainants in the case of *Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim* argued that the two companies were acting in violation of competition law by charging excessive prices for some of their ARVs to the detriment of patients.²⁷⁵ The complainants argued that even when provision was made for R&D costs, higher profits and licensing fees, the prices of these patented medicines remained excessive. The complaint was

²⁷⁰ Chapter two of the Competition Act contains a number of provisions that could be used to challenge anticompetitive practices in the health sector broadly and in the pharmaceutical sector in particular. The chapter deals with ‘prohibited practices’ in two parts: ‘Restrictive Practice’ in Part A and ‘Abuse of a Dominant Position’ in Part B. In Part A, the Competition Act prohibits certain restrictive horizontal practices, such as price fixing between competitors, as well as certain ‘restrictive vertical practices’, such as agreements between a supplier and a customer relating to minimum resale prices. Part B deals with four main categories of prohibited abuse of dominance.

²⁷¹ See Mathews (2011) “Intellectual Property, Human Rights and Development: The Role of NGOs and Social Movements” Edward Elgar, Publishing Ltd, UK which contains a lengthy discussion of civil society groups in Brazil, South Africa and India in advocating and litigating for increased access to treatment.

²⁷² Three civil society groups, the Aids Law Project (ALP), Treatment Action Campaign (TAC) and MSF are predominantly responsible for efforts to competition law to reduce ARV prices in South Africa.

²⁷³ See, for example, *National Association of Pharmaceutical Wholesalers and Others v Glaxo Wellcome (Pty) Ltd and Others* (Competition Appeal Court, case no: 29/CAC/JUL03, 18 February 2005, dealing with interim relief in a matter considering vertical agreements between pharmaceutical manufacturers and exclusive distributors.

²⁷⁴ See Avafia et al for a more comprehensive discussion of the complaint submitted to the Commission. See also Nguyen T, (2010) “Competition Law, Transfer of Technology and the TRIPS Agreement: Implications for Developing Countries” Edward Elgar Limited from 184-188 for a discussion of the Hazel Tau complaint as well as two subsequent complaints filed by the TAC against Bristol-Myers Squibb in 2005 and Merck in 2007.

²⁷⁵ In addition to the TAC, the complaint was lodged by the ALP on behalf of a number of people living with HIV, health care workers treating people living with HIV and a number of trade unions.

accompanied a strategic public relations campaign which included the publication of materials, including the booklet²⁷⁶ numerous press releases, fact sheets and advertisements.²⁷⁷

After a year-long investigation, the Competition Commission had found sufficient evidence of excessive pricing and two additional grounds (both linked to the failure of GSK and Boehringer Ingelheim to license generic manufacturers) to support the referral of the complaint to the Competition Tribunal. By early December 2003, within two months of the Commission's referral announcement, both companies had entered into separate settlement agreements with the complainants and the Commission with the result that more competitors were able to enter the market, pay lower royalties to the patent holders and sell their products throughout sub-Saharan Africa.²⁷⁸

A little more than a year after the settlement agreements had been concluded, the ALP wrote a letter of demand On 15 February 2005 to the originator pharmaceutical company Bristol-Myers Squibb (BMS) in which it threatened to bring an excessive pricing complaint against BMS for excessive pricing of amphotericin B, a medicine used to treat cryptococcal meningitis, a common cause of death among people living with HIV in Africa. While the medicine in question was no longer under patent, BMS still had a de facto monopoly for its product in South Africa for which it charged high prices in comparison to other countries including some developed country markets.²⁷⁹ Mindful of the finding of the Competition Commission complaint in the matter of Hazel Tau, the ALP demanded that BMS reduce its prices to match those being charged in

²⁷⁶ See Beresford B, (2003), 'The Price of Life: Hazel Tau and Others v GlaxoSmithKline and Boehringer Ingelheim' [Online] Available:

<http://www.alp.org.za/modules.php?op=modload&name=News&file=article&sid=222> at 41.

²⁷⁷ See the TAC advertisement captioned 'Support Legal Action against GlaxoSmithKline and Boehringer Ingelheim!' that appeared in a daily South African newspaper. The advertisement is available online at:

<http://www.tac.org.za/Documents/Pamphlets/TACBUSDAYAD.jpeg>.

²⁷⁸ The terms and conditions agreed to in the settlement agreements are available at:

http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm. See also Wilson Kinsley R, (2009). At the time that the complaint was lodged, both companies had negotiated voluntary licences with the South African generic pharmaceutical company Aspen Pharmacare albeit with conditions which restricted competition. The license concluded between GSK and Aspen for example, restricted the latter to the public sector market and required percent royalty fees to be paid to GSK. The settlement agreement extended sales to the private sector, authorised Aspen to supply all sub-Saharan African countries and capped the royalty rate at no more than percent. By the end of June 2007, four generic companies were selling generic zidovudine in South Africa, given the expiry of GSK's patent in 2006.

²⁷⁹ According to the letter of demand, generic amphotericin was being sold in Brazil for a fraction of the South African price. The same product was also available in the UK at less than 30 percent of the public sector price in South Africa.

developing countries similar to South Africa such as Brazil. A little more than two months later, the prices of amphotericin B had dropped by 80 percent in the public sector and 85 percent in the private sector.²⁸⁰

The South African Competition Act was used a third time by treatment activists in November 2007 to reduce the cost of efavirenz, a first-line ARV patented in South Africa by Merck Sharp and Dhome (MSD), the local subsidiary of the multinational pharmaceutical company Merck. MSD had concluded a voluntary license in 2004 with the South African generic manufacturer Thembalami Pharmaceuticals²⁸¹ to bring stand-alone efavirenz products to the market and granted a second license to the South African generic company Aspen Pharmacare in 2005 on similar terms and conditions after Thembalami ceased operating.²⁸² While a third license was negotiated with the local generic company Adcock Ingram in August 2007, The ALP acting on behalf of the TAC asserted that MSD had refused to grant more voluntary licenses, noting that robust competition for efavirenz,²⁸³ which accounted for up to a third of the national HIV treatment tender costs as late as 2008²⁸⁴ remained unlikely. As with the other complaints, the matter was settled between the parties with MSD agreeing to conclude voluntary licenses with four generic companies to supply efavirenz on a royalty free basis within South Africa, and to 10 other countries in the region.²⁸⁵

²⁸⁰ Ibid Avafia et al. See also, Kudlinski A, 'Harmonizing policies for health care, the pharmaceutical industry and intellectual property: the South African experience' in Abbott F, Correa C, and Drahos P, (2013) "Emerging Markets and the Patent World Order", Edward Elgar Publishing (Ltd) at 280. While Kudlinski argues at 279 that the cases brought by treatment activists against BMS, GSK and Boehringer Ingelheim were disputable for various reasons including the absence of compulsory licensing remedies in the competition Act and possible difficulties that may have been faced in establishing marketing dominance by the originator companies in question, he concedes that the eventual outcome was a resulting price reduction of both patented and off-patent medicines used to treat HIV.

²⁸¹ Thembalami pharmaceuticals was a joint venture between the South African generic company Adcock Ingram and the Indian company Ranbaxy. The joint venture collapsed before Thembalami sold any generic efavirenz on the South African market.

²⁸² An information note issued by the TAC observed that at the time of the complaint in late 2007, Aspen products had not received marketing approval from the South African Medicines Control Council (MCC).

²⁸³ The Statement of complaint is [Online] Available at: <http://www.wcl.american.edu/pijip/documents/complaint.pdf>. The TAC information note is [Online] available at: <http://www.tac.org.za/community/node/2127>

²⁸⁴ Ibid Kudlinski at 278.

²⁸⁵ Angola, Botswana, DRC, Lesotho, Madagascar, Mauritius, Namibia, Seychelles, Swaziland and Zimbabwe. Details of the settlement agreement can be found in an information note developed by the TAC dated 1 June 2008 [Online] Available at: <http://www.tac.org.za/community/node/2329>

The implications of the complaint against MSD on efavirenz prices are less clear. Kudlinski²⁸⁶ has argued that efavirenz still accounted for a large portion of the 2008 national ARV tender while the TAC has noted that the cost differential between the lowest international price Merck sold a year's supply of efavirenz for was approximately US\$ 237 per patient per year while the lowest generic price at the time was US\$ 150 per patient per year.

In 2012, a complaint was received by the Competition Commission by MSF concerning an alleged incident of anti-competitive behaviour in the form of an agreement concluded between two generic manufacturers Mylan (Inc.) to Aspen Pharmacare, for the sale and supply of APIs in the country. MSF alleged in its complaint that the agreement, valid until 2016, essentially made Aspen the exclusive supplier of FDCs in the country, and prevented Mylan from selling the APIs in the South African market, and from supplying any other pharmaceutical manufacturers in the country with the same API.²⁸⁷ In September 2014, the Competition Commission concluded that the agreement did not constitute a violation of the Competition Act. It also found that the agreement between Aspen and Mylan did not prevent Aspen's competitors from sourcing similar products elsewhere, nor did it constitute market allocation, a specific ground under the Act of anti-competitive conduct.²⁸⁸

3.5 The August 30 2003 Agreement

As discussed above in chapter two, the August 30 2003 Agreement, concluded after two years of divisive negotiations at the WTO TRIPS Council is a temporary waiver to resolve the problem that WTO Members with insufficient domestic pharmaceutical manufacturing capacity faced because

²⁸⁶ Ibid at 278.

²⁸⁷ See document DAF/COMP/WD (2014)68 from the South African government to the Competition Committee of the Department for Financial and Enterprise Affairs of the Organisation for Economic Co-operation and Development (OECD) dated 19 May 2014 for more information on the complaint.

²⁸⁸ See 'Commission non-refers complaint by Doctors Without Borders' in an October Newsletter [Online] Available:

<http://www.cliffedekkerhofmeyr.com/export/sites/cdh/en/news/publications/2014/competition/downloads/Competition-Alert-1-October-2014.pdf>

of the limitations of Article 31(f) of the TRIPS Agreement. As previously noted, the Agreement includes a number of administratively onerous requirements for importing and exporting countries to meet before the exportation of medicines manufactured under compulsory license predominantly for export can take place. The fact that it took several years since the Agreement was concluded for a country to attempt to use the mechanism at a time when ART prices were still relatively expensive justifies the criticism levelled by civil society organizations and others,²⁸⁹ about the practicability of the Decision. It is also noteworthy that more than a decade after the Agreement was concluded, it remains a temporary waiver because it has not been ratified by two-thirds of WTO Members.

3.5.1 Rwanda and Canada's use of the August 30 2003 Agreement

The process behind Rwanda's use of the 30 August 2003 Agreement dates back to the amendment of Patent Act in Canada in 2004.²⁹⁰ With the passing of enabling legislation in Canada, MSF, which had an HIV treatment centre in Rwanda, persuaded Apotex, Canada's largest generic manufacturing company to produce Apo-Triavir[®], then a new FDC of zidovudine, lamivudine and nevirapine.²⁹¹ Interested in determining the practicability of the Mechanism, MSF indicated that it would attempt to use the Canadian Access to Medicines Regime (CAMR) to place an order for the Apotex product for use in one or more of its AIDS treatment projects in the field.²⁹² Apotex produced Apo-Triavir[®] which was duly granted marketing approval by Health Canada and approved by the WHO's pre-qualification program in 2006. Even though it had encouraged the

²⁸⁹ See for instance an MSF Press Release on 11 September 2003 at the WTO Cancun Ministerial [Online] Available: <http://www.cptech.org/ip/wto/p6/msf09112003.html>

According to a News story by the Wall Street Journal of 2 September 2003 entitled 'WTO Drug Pact Lifts Trade Talks – Landmark Deal Provides Medicines to Poor Nations', Even the then EC Trade Commissioner Pascal Lamy offered little more than a cautious endorsement at the time noting:

"We all have to be very modest. We have solved about 10 percent of the problem of access to medicines by developing countries.

²⁹⁰ *An Act to Amend the Patent Act and the Food and Drugs Act (Jean Chrétien Pledge to Africa)*, S.C. 2004, c. 23, [Online] Available: www.canlii.org/ca/as/2004/c23/. Regulations to give effect to the 2004 Act were passed in 2005. See *Use of Patented Products for International Humanitarian Purposes Regulations*, S.O.R. 2005/243; *Food and Drugs Regulations* (1402 — Drugs for Developing Countries), S.O.R. 2005/141; *Medical Devices Regulations* (Developing Countries), S.O.R. 2005/142, all in the *Canada Gazette (Part II)*, Vol. 139 (No. 11), June 1, 2005, all available via <http://canadagazette.gc.ca/partII/2005/20050601/html/index-e.html>.

²⁹¹ Elliott R, (2008) 'Delivery past due: global precedent set under Canada's Access to Medicines Regime' HIV/AIDS Policy & Law Review Vol. 13(1) at 2 [Online] Available: <http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=1345>

²⁹² Ibid Elliott at 2.

development of a product, MSF initially struggled to persuade eligible importing WTO Members to use the Mechanism, which prompted increase criticism over its effectiveness.

After interventions by the Clinton Foundation's HIV/AIDS Initiative (CHAI),²⁹³ the government of Rwanda²⁹⁴ became the first country to notify the WTO Secretariat²⁹⁵ of its intention to use the Mechanism created by the August 30 Agreement²⁹⁶ noting that:

“Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of Triavir.”

The notification concluded that because Rwanda is classified as an LDC, the government would not enforce any patent rights that may have been granted within Rwanda's territory regarding the product. This notification prompted Apotex into attempting to reach a voluntary licensing agreement on reasonable terms and conditions with the Canadian patent holders of zidovudine, lamivudine and nevirapine, namely: GSK, the Wellcome Foundation, Shire Biochemical, and Boehringer Ingelheim. The negotiations for a voluntary license were protracted, with Apotex alleging that the patent holders were intentionally stalling the negotiations, a claim the patent holders denied.²⁹⁷ After weeks of negotiations with no agreement between Apotex and the patent holders, Apotex applied for a compulsory license²⁹⁸ which was granted on 19 September 2007. The license authorised Apotex to produce and export the quantity notified by Rwanda which amounted to 15.6 million tablets over a maximum period of two years.²⁹⁹ In October 2007, the

²⁹³ Ibid Elliott. See also Webber A, and Mills L, (2010) 'A One Time Only Combination: Emergency Medicine Exports Under Canada's Access to Medicines Regime, Health and Human Rights Journal, Volume 12, 1 [Online] Available: <http://www.hhrjournal.org/index.php/hhr/article/view/209/303>

²⁹⁴ More specifically, the Centre for treatment and Research on Aids (TRAC).

²⁹⁵ On 17 July 2007.

²⁹⁶ Government of Rwanda, "Notification under Paragraph 2(a) of the Decision of August 30 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health", Document IP/N/9/RWA/1, 19 July 2007.

²⁹⁷ Tsai G, (2009) 'Canada's Access to Medicines Regime: Lessons for Compulsory Licensing Schemes' Virginia Journal of International Law, Vol. 49:4 at 1064.

²⁹⁸ See Apotex, "Application pursuant to Section 21.04 of the Patent Act," 4 September 2007 [Online] Available: http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p4-e.html.

²⁹⁹ Commissioner of Patents (Canadian Intellectual Property Office), "Authorization Under Section 21.04 of the Patent Act," 19 September 2007. Available at: http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p4-e.html

Canadian WTO representative notified the WTO Secretariat that the compulsory license had been issued.³⁰⁰

The export process was then delayed by the Rwandan government issuing a government tender for the purchase of Apo Triavir® (a measure required by Rwandan law for government procurement orders). The tender was opened in October 2007, inviting interested parties to submit bids for the supply of the ARVs. The tender closed at the end of November. Apotex then had to out-compete other generics manufacturers vying for the contract.³⁰¹ In order to do so, it submitted a bid to the Rwandan government quoting a price of US\$0.195 per tablet which amounted to US\$146 per patient per year, lower than the then lowest publicly reported generic price of US\$176 per patient per year.³⁰² A further five months elapsed before, on 7 May 2008, Apotex announced that it had won the government tender and that the Rwandan government had taken a decision to purchase its product.³⁰³ The first shipment to Rwanda was made in late September 2008, with a second shipment following a year later on 18 September 2009.³⁰⁴ While this importation by the Government of Rwanda to some degree, constitutes a success, many questions remain unanswered about the effectiveness of the mechanism in general, and the CAMR in particular. According to Tsai:

*“CAMR is a paradigm example of legislation that gives developed countries—precisely those with the means of production—a tool to alleviate the global health crises plaguing much of the least developed world. By learning from the mistakes of CAMR, other developed nations may pass legislation that utilizes the compulsory licensing provisions of the TRIPS Agreement in a more effective manner.”*³⁰⁵

³⁰⁰ Government of Canada, “Notification under paragraph 2(C) of the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,” WTO Doc. IP/N/10/CAN/1, 5 October 2007.

³⁰¹ Ibid Tsai at 1078.

³⁰² See MSF, (2007) ‘*Untangling the Web of Price Reductions* (10th ed.) [Online] Available: <http://www.accessmed-msf.org/main/hiv-aids/price-guide-to-aids-drugs> .

³⁰³ According to a press release by the Canadian HIV/AIDS Legal Network entitled “Canada finally poised to deliver on promise of affordable medicines to developing countries?” 7 May 2008 [Online] Available: <http://www.aidslaw.ca/media>

³⁰⁴ See Press Release by Apotex Inc. “Second Shipment of Life saving aids Drug Leaving for Africa” 18 September 2009 [Online] Available: <http://www.apotex.com/global/about/press/20090918.asp>

³⁰⁵ Ibid at 1096.

According to Elliott,

*“Canada’s Access to Medicines Regime must be fixed so that it can be used in future to export lower-cost, generic drugs to countries dealing with the AIDS pandemic and other public health problems.... Unnecessary red tape has been suffocating this law since it was passed in 2004.”*³⁰⁶

The government of Rwanda has never offered a public assessment of its experience in using the mechanism including the five month delay caused by the government procurement process despite subsequent discussions at the WTO Council for TRIPS on the workability of the Agreement. The absence of information has made it difficult to determine whether capacity constraints at the national level or the administrative requirements of the Agreement were the primary impediment in the use of the Mechanism which remains unused since.

3.6 Conclusion

As examined above, there have been several attempts by countries in eastern and southern Africa to use public health related TRIPS flexibilities to decrease treatment costs, some more successful than others. Table 1 below documents instances where public health related TRIPS flexibilities were used to reduce prices of essential medicines:

Table 1: The Use of Public Health Related TRIPS Flexibilities in Eastern and Southern Africa

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³⁰⁶ According to a press release by the Canadian HIV/AIDS Legal Network *Groups Rally on Parliament Hill for Access to Life Saving Medicines* dated 29 September 2010 [Online] Available:

<http://www.aidslaw.ca/publications/interfaces/downloadDocumentFile.php?ref=1094>

For a comprehensive list of statements, research and submissions led by the Canadian HIV/AIDS Legal Network to reform the CAMR, refer to: <http://www.aidslaw.ca/EN/camr/index.htm>

TRIPS Flexibility	Country, Year	Antiretroviral	Patent Holder	Royalty	Price Impact
Government use	Zimbabwe 2003	zidovudine, lamivudine and combivir	GSK	unclear	Yes
Government use	Mozambique 2004	zidovudine, lamivudine and nevirapine	GSK, Boehringer Ingelheim	2% net sales	No
Government use	Zambia 2004	zidovudine, lamivudine and nevirapine	GSK, Boehringer Ingelheim	2.5% net sales	No
Competition law	South Africa 2002	zidovudine, lamivudine and nevirapine	GSK, Boehringer Ingelheim	Up to 5%	Yes
Competition law	South Africa 2005	amphotericin B	BMS	n/a	Yes
August 30 2003 Mechanism	Rwanda 2007	zidovudine, lamivudine and nevirapine	GSK, Boehringer Ingelheim	0.5%	Yes

The table does not include instances discussed above in this chapter where the threat to use TRIPS flexibilities either by government officials may have resulted in reduced prices as occurred in Kenya in 2004. Even with this consideration, the table does not contain many instances where government authorities successfully used public health related TRIPS flexibilities to increase treatment access. Public health related TRIPS flexibilities will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs.

An obvious conclusion from Table 1 must be that the majority of attempts to reduce treatment costs in the region have centred around three ARVs: zidovudine, lamivudine and nevirapine. This is explained by the fact that at the time, these three ARVs constituted the most regularly used medicines in the region and formed the core of the recommended regimen in the WHO 2003

treatment guidelines.³⁰⁷ For reasons of increased adherence, the 2013 WHO treatment guidelines recommend the use of a single tablet ARV regimen comprising of tenofovir and lamivudine and one of either emtricitabine or efavirenz. While most sub-Saharan African countries pay among the lowest prices for ARVs in the world over time, more patients will require second, and eventually, third line treatment, both of which are distinctly more expensive than first line treatment.

The first hypothesis advanced in chapter was that the incorporation and use of public health related TRIPS flexibilities has not been needed to treat patients in eastern and southern African countries because most patients on ART in the region predominantly are still on first-line ART regimens, which are both affordable, and presently funded by bilateral and multilateral donor institutions such as the GFATM and PEPFAR. However, public health related TRIPS flexibilities will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs increasingly being patented in countries with significant pharmaceutical manufacturing capacity. This hypothesis is supported by the cost of treatment of newer generation ARVs used in second and third line treatment.

The second line treatment recommended by WHO is a combination of zidovudine, lamivudine and lopinavir with ritonavir or atazanavir and ritonavir. At the end of 2012, the median price for this recommended regimen was US\$ 451 per patient per year in lower-middle-income countries and US\$ 442 in upper-middle-income countries, but with significant price variations depending on the country.³⁰⁸ There are a growing number of instances where second line treatment has failed in patients on ART, thus necessitating third line treatment which is drastically more expensive, with combinations containing raltegravir, etravirine or boosted darunavir costing more than US\$2 000

³⁰⁷ Other first line ARVs included stavudine, which was eventually removed from the WHO list of recommended ARVs because of its high levels of toxicity, and efavirenz, which was under patent in most countries, and remained as a consequence comparatively expensive. The 2003 WHO Treatment Guidelines are [Online] available at: http://www.who.int/hiv/pub/prev_care/en/arvrevision2003en.pdf?ua=1

³⁰⁸ See WHO, UNICEF, UNAIDS (2013) *Global Update on HIV Treatment 2013: Results, Impacts and Opportunities*, Geneva at 99 [Online] Available: http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2013/20130630_treatment_report_en.pdf

per patient per year in select low income countries, approximately 18 times the lowest price for first-line regimens.³⁰⁹

The first hypothesis is further supported by the degree of multilateral funding countries with high burdens of AIDS have received over the past year. Around the time the first government use order in the region was being issued, Zimbabwe had just started receiving its first AIDS grant from the GFATM. In a little more than a decade, US\$ 450 million in AIDS funding has been disbursed to Zimbabwe from the GFATM. Zimbabwe now has one of the world's largest national ART programmes with an estimated 670 000 people on ART. The two countries who next attempted to issue government use orders in 2004 were Mozambique which is home to approximately 500 000 people on ART and Zambia which has approximately 530 000 patients on ART. Since 2003, Mozambique has received almost US\$ 450 million and Zambia US\$ 675 million in AIDS funding from the GFATM.

The role of the GFATM, and PEPFAR in reducing ART costs, and by consequence, removing the need for countries in the region to self-finance their AIDS responses by, *inter alia*, the greater use of public health related TRIPS flexibilities should not be under-estimated. Once countries in the region began consistently accessing multilateral funding to sustain treatment programmes, the need to use TRIPS flexibilities evaporated, at least in the short term. This assertion is supported by the fact that since Rwanda's use of the 30 August 2003 Decision in 2008, no other country in eastern and southern Africa has attempted to use public health related TRIPS flexibilities to increase treatment access.

An inadvertent consequence of the multilateral funding institutions playing such a key role in shaping the ARV market in the region must be the its negative impact on local pharmaceutical manufacturers in the region despite efforts by regional and local authorities to promote local pharmaceutical manufacturing as discussed below in chapter six. The issuing of compulsory licenses and government orders did not have the desired consequence of stimulating local pharmaceutical production in Zimbabwe, Kenya, Zambia and Mozambique. If anything, the inability of a local pharmaceutical company like Varichem which successfully managed to

³⁰⁹ Ibid WHO, UNICEF, UNAIDS.

navigate the WHO pre-qualification process in order to compete with Indian generic manufacturers on price, coupled with the failure of governments to support local producers through domestic financing have resulted in a number of pharmaceutical manufacturers in the region being excluded from supplying the market.

The second hypothesis advanced in chapter one is that there are capacity constraints within the relevant government departments in eastern and southern Africa which hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and the use of these flexibilities when needed. This hypothesis is affirmed by the clear challenges faced by the government authorities in Zambia and Mozambique in attempting to employ non-voluntary licenses to introduce locally produced ARVs into their markets. First, there is unreliable patent information at the national level which makes it difficult to establish which patents are valid. This situation is exacerbated by a lack of coherence between regional patent examiners at ARIPO and national patent offices. Further incoherence between countries in the region and ARIPO through the substantive examination of patents will be discussed in the next three chapters.

Another conclusion to be drawn from this chapter is that competition law depending on the national context can be an important remedy in reducing treatment costs. First, it enables non-government actors to act in a way that patent legislation cannot, given the functions and responsibilities specifically conferred on government officials in the latter. The relative ease in the use of competition law in south Africa stands in contrast to Rwanda's use of the August 30 2003 Mechanism. Although a substantial portion of the delay in using the August 30 2003 Mechanism in Rwanda was as a result of an internal government procurement process, the fact that the Mechanism depends on the regulations of an exporting country, as was the case with CAMR should be a cause for concern for other eastern and southern African governments, particularly as the provisions in India's Patents Amendments Act giving effect to the mechanism remain untested.

Because Rwandan government officials have not offered an assessment of whether the challenges faced in using the August 30 2003 Mechanism were caused by capacity constraints at the national level, an assessment in this regard is not possible. The larger question, as raised in chapter two, remains whether the August 30 2003 Decision in its current form is an appropriate solution for

countries without sufficient manufacturing capacity or whether the African Group and other countries with insufficient local pharmaceutical manufacturing capacity should prioritise efforts to re-open the negotiations to find an alternative to the problem posed by Article 31(f) of the TRIPS Agreement.

The country studies which will form the next two chapters will explore in more detail whether the public health related TRIPS flexibilities have been fully incorporated within the legislations of Tanzania, and South Africa and will further test the three hypotheses advanced in chapter one.

4 Industrial Property and Related Legislation Relevant to Treatment Access in the United Republic of Tanzania

I am sometimes a fox and sometimes a lion. The whole secret of government lies in knowing when to be the one or the other.

Napoleon Bonaparte

4.1 Tanzania: A Unification of Two Territories

The United Republic of Tanzania as the name suggests, is a union of two territories with distinct histories. Mainland Tanzania came under German rule in the late nineteenth century with the occupation of modern day mainland Tanzania, Burundi and Rwanda, which were merged into German East Africa. After World War I, German East Africa was placed under the trusteeship of the UK with the exception of a relatively small territory ceded to Belgium, now modern day Burundi and Rwanda. Tanganyika became independent in 1961 following a relatively peaceful transition to independence.

Zanzibar by comparison has had a more turbulent modern history. After centuries of occupation by Persian, Arab and Portuguese rulers, Zanzibar came under the ownership of the Sultan of Oman in 1898 and was primarily known as a transit hub for the slave trade and for the production of cloves. Zanzibar became a British protectorate in 1890³¹⁰ and was ruled by a succession of governors until its independence in December 1963 when it became a constitutional monarchy under the leadership of the Sultan of Zanzibar. A mere few weeks after independence, a bloody revolution occurred resulting in the deaths of several thousand citizens of Indian and Arab origin. On 26 April 1964, the newly installed Revolutionary Government of Zanzibar and Pemba³¹¹ united with Tanganyika³¹² to become known as the United Republic of Tanganyika and Zanzibar, a name that was later shortened to the United Republic of Tanzania.³¹³ Reasons offered for the unification

³¹⁰ With the conclusion of the Heligoland-Zanzibar Treaty of 1890.

³¹¹ Pemba being a small Island to the north-east of Zanzibar.

³¹² Tanganyika had become independent on 9 December 1961 from UN Trusteeship administered by the UK.

³¹³ See the Union of Tanganyika and Zanzibar Act 22 of 1964. The revision of the name took place on 29 October 1964.

have ranged from the geographical proximity and close ties between the two countries, to shared political ideologies and the prevailing spirit of Pan-Africanism at the time.³¹⁴

As part of the unification agreement with Tanganyika, the former Revolutionary Government of Zanzibar retained a significant degree of autonomy and is directly responsible for affairs not listed in the articles of Union³¹⁵ including the Zanzibar Registry of Trade Marks and Patents³¹⁶ and the Zanzibar Food and Drugs Board. Mainland Tanzania on the other hand relies on the Business Registration and Licensing Agency (BRELA) situated within the ministry of Trade and Industry to regulate industrial property issues while the competent drug regulatory authority is the Tanzania Food and Drugs Authority (TFDA). Given the presence of more than one regulatory authority overseeing the administration of health technologies and intellectual property, this chapter will examine the legislative frameworks of mainland Tanzania and Zanzibar separately. For the purposes of this chapter, where the term ‘Tanzania’ is used, it refers the combination of mainland Tanzania and Zanzibar.

This chapter tests the first hypothesis advanced in chapter one, namely that the incorporation and use of public health related TRIPS flexibilities has not been needed to treat patients, but will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs, by following the process of intellectual property related law reform in both Mainland Tanzania and Zanzibar and assessing the outcomes and examining the extent to which the flexibilities are reflected in national legislation. In testing the second hypothesis advanced in chapter one, namely that capacity constraints within the relevant government departments in eastern and southern Africa which hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and the use of these flexibilities when needed, this chapter examines the national institutions whose mandates relate to

³¹⁴ See Musa A, (2005) ‘The Union Between Tanganyika and Zanzibar: Legality of Matters Outside the Articles of Union’ [Online] Available at: http://www.zanzinet.org/files/legality_union.pdf

³¹⁵ Matters initially governed by the Union include Constitutional issues, external affairs, defense, police, emergency powers, citizenship, immigration, external trade and borrowing, the public service, income tax, corporation tax, customs and excise duties and harbors, civil aviation, posts and telegraph.

³¹⁶ The Registry of Trademarks and Patents is housed within the Ministry of Justice and Constitutional Affairs.

the implementation of public health related TRIPS flexibilities and assesses some of the capacity constraints they face.

Finally, the chapter examines the existing legislative and regulatory framework in assessing whether the third hypothesis advanced in chapter one, namely that a significant degree of policy incoherence in the form of national level legislation exists, which, if not addressed by law reform and increased co-ordination, could undermine the incorporation and use of TRIPS flexibilities at the national level. The chapter also explores the incoherence which exists between national intellectual property related objectives aimed to facilitate access to treatment and regional intellectual property policies and practices, particularly ARIPO and draws conclusions on how some of this misalignment could be addressed.

4.2 The Public health Situation in Tanzania and Access to Essential Medicines

Tanzania was estimated to have a population of approximately 45 million people as of mid-2012,³¹⁷ with an estimated 1.5 million people living with HIV at the end of 2012 and an estimated adult HIV prevalence of 5.1 percent.³¹⁸ While the level of HIV infection has decreased from levels of a few years ago, approximately 80 000 people lost their lives in 2012 alone.³¹⁹ The Ministry of Health and Social Services with extensive assistance from the international community³²⁰ has established care and treatment services across the country. While an estimated 1.3 million people living with HIV in Tanzania were in need of ART according to the WHO 2013 treatment guidelines, only a reported 399 000 people were receiving ART as of the end of 2012.³²¹ Tanzania's AIDS response, including treatment and prevention programmes are almost exclusively dependent on multilateral funding, primarily from the GFATM and PEPFAR which together, accounted for approximately 95 percent of the foreign funding of the HIV response in

³¹⁷ According to the National Bureau of Statistics in its 2012 report "Tanzania in Figures" [Online] Available: http://www.nbs.go.tz/nbs/takwimu/references/Tanzania_in_figures2012.pdf

³¹⁸ See UNAIDS Tanzania country website [Online] Available: <http://www.unaids.org/en/regionscountries/countries/unitedrepublicoftanzania/>

³¹⁹ Ibid UNAIDS.

³²⁰ See USAID Tanzania HIV/AIDS Health Profile of 2010 [Online] Available: http://www.usaid.gov/our_work/global_health/aids/Countries/africa/tanzania.pdf

³²¹ See UNAIDS (2013). The Global Fund which contains more timely updates of estimated HIV prevalence levels notes that approximately 440 000 people are on ART in Tanzania as of June 2014.

Tanzania in 2010.³²² Since its inception in 2002, the GFATM is reported to have spent in excess of US\$ 582 million on HIV prevention and treatment programmes in Tanzania,³²³ while PEPFAR has spent US\$ 1.9 billion on AIDS programming in Tanzania between 2004 and 2011.³²⁴ ARVs appear to be affordable, with the median cost per patient per year less than US\$ 100 per patient per year for first line ART, which at this stage, constitutes the vast majority of patients in Tanzania. Recent studies appear to suggest that the number of patients on second and third line ART in Tanzania is less than five percent of patients on treatment.³²⁵

As with most countries, HIV and TB co-infection is on the increase in Tanzania, where approximately 80 000 people are living with TB in 2010, of which 37 percent tested HIV positive.³²⁶ As noted above in chapter one, Tanzania is an LDC with a comparatively low industrial base and nascent local pharmaceutical industry. It is a net importer of health technologies, a situation unlikely to change in the foreseeable future. The country is a member of both the EAC and SADC, each with different regional initiatives on intra-regional co-operation treatment access.

4.2.1 A Profile of the Pharmaceutical Industry of Tanzania

As noted above in chapter one, the vast majority of ARVs in use in eastern and Southern Africa are produced by Indian generic manufacturers. The question of capacity development for the promotion of local manufacturing is one that has resulted in different approaches over time. In the 1970s and 1980s, local pharmaceutical production in sub-Saharan Africa was encouraged by governments and international organisations because it was seen as an important yardstick to determine economic self-sufficiency, to reduce imports and loss of foreign exchange, to create employment and to gain national prestige. However, from the late 1980s, as unfavourable studies

³²² Ibid USAID 2010.

³²³ According to information obtained from the GFATM website on 19 June 2014 [Online] Available: <http://portfolio.theglobalfund.org/en/Country/Index/TZA>

³²⁴ According to the PEPFAR Tanzania country profile [Online] Available: <http://www.pepfar.gov/documents/organization/199593.pdf>

³²⁵ See Ramadhani H, et al (2014) 'Association of First-line Antiretroviral Therapy Adherence with Adherence to Second-line Antiretroviral Therapy Among HIV-infected Patients in Tanzania' Open Forum Infectious Diseases Advance Access, Oxford University Press.

³²⁶ See WHO (2011) Tuberculosis Profile of the United Republic of Tanzania [Online] Available: https://extranet.who.int/sree/Reports?op=Replet&name=%2FWHO_HQ_Reports%2FG2%2FPROD%2FEXT%2FTBCountryProfile&ISO2=TZ&outtype=html

on the feasibility and potential for local production in developing countries emerged, optimism on the part of donors and international organisations cooled significantly.³²⁷ The recent increase in regional initiatives promoting local pharmaceutical production as will be discussed below in Chapter six are an indication that the pendulum has swung again in favour of local pharmaceutical production. The World Bank has categorized pharmaceutical companies in LMICs as follows:³²⁸

- (i) Subsidiaries of multinational originator companies operating in the region;
- (ii) Large generic companies, predominantly based in India with an extensive portfolio of products that comply with international standards including the WHO Good Manufacturing Practice (GMP) operating in the region through local subsidiaries;³²⁹
- (iii) Locally registered generic companies aiming to supply the domestic market with some exports, usually to neighbouring countries with some compliance with WHO GMP standards; and
- (iv) Small scale local manufacturers who have modest operations supplying local and occasionally, regional markets with the majority of their medicines not meeting GMP standards.

A 2010 study found that Tanzania imported about 70 percent of its national drug requirements while local production accounted for about 30 percent,³³⁰ a number that had reportedly declined to approximately 20 percent of market share in 2013.³³¹ As of 2008, out of the 3388 drugs registered for sale by the Tanzania Food and Drugs Administration (TFDA), 269 products were

³²⁷ See Losse K, Schneider E, Spennemann C, (2007) 'The Viability of Local Pharmaceutical Production in Tanzania.' Deutsche Gesellschaft für Technische Zusammenarbeit, Eschborn [Online] Available: <http://www.gtz.de/de/dokumente/en-local-pharmaceutical-production-tanzania-2007.pdf>

³²⁸ See Seiter A, (2005) A 'Pharmaceuticals: Local Manufacturing' HNP Brief No 3, World Bank [Online] Available: http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1109774792596/HNPBrief_3.pdf

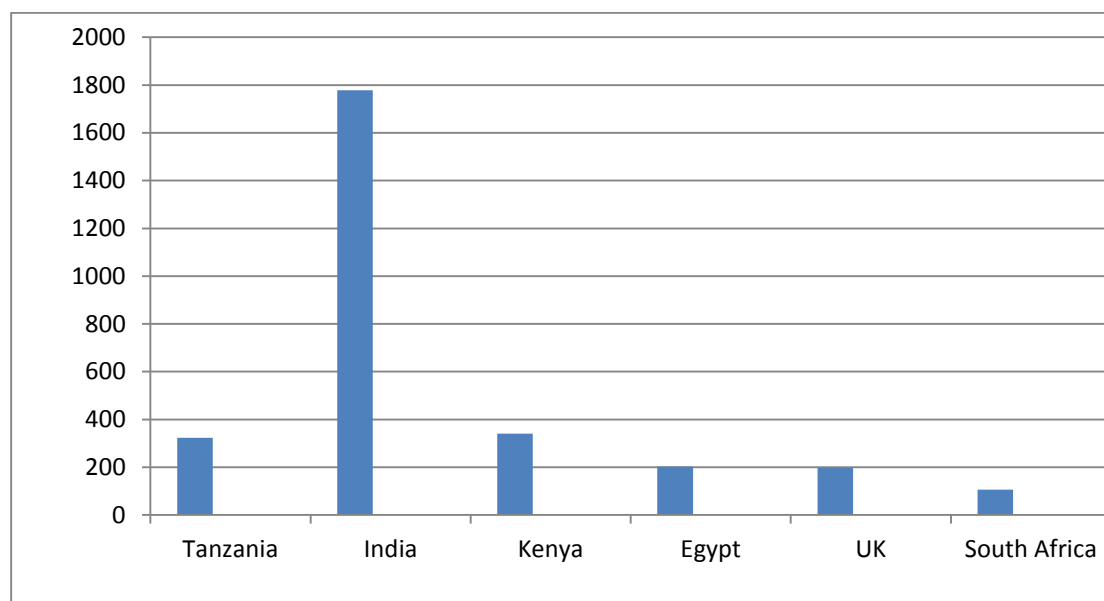
³²⁹ Chaudhuri S, (2008) 'Indian Generic Companies, Affordability of Drugs and Local Production in Africa with special Reference to Tanzania' IKD Working Paper 37, Open University. Chaudhuri notes in his paper that Indian companies have set up some manufacturing plants in Africa primarily through joint ventures with local companies – Cipla in South Africa, Uganda and Morocco, Cadila in Ethiopia, Ajanta Pharma in Mauritius, and Ranbaxy in Nigeria and South Africa.

³³⁰ Mhamba R, and Mbiringenda S, (2010). *The Pharmaceutical Industry and Access to Essential Medicines in Tanzania*. <http://www.equinetafrica.org/bibl/docs/DIS83TZN%20medicines%20mhamba.pdf>.

³³¹ Wangwe S, et al (2014) 'Reversing Pharmaceutical Manufacturing Decline in Tanzania: Policy Options and Constraints' Brief 43 [Online] Available: http://www.repoa.or.tz/documents/REPOA_BRIEF_43.pdf

registered by Tanzanian local generic manufacturers.³³² Tanzania imports medicines from as many as 40 other countries, which accounts for the remaining 92 percent of registered products.

Figure 1: Number of Medicines Registered by TFDA



Source: TFDA

None of the Tanzanian local manufacturers have the capacity to produce the APIs required for medicines formulation. The APIs are imported from traditionally large manufacturers of APIs based in India and China. The largest pharmaceutical company in Tanzania and one of the largest and fastest growing in the EAC is Shelys pharmaceuticals Ltd, which would fit into the third category of World Bank classification. Established in 1984 in Dar es Salaam, with a portfolio which includes exporting pharmaceutical products to neighbouring countries including Kenya, Uganda and Zambia,³³³ Shelys accounts for approximately 21 percent of the local market³³⁴ and manufactures more than 90 products including anti-malarial medicines, antibiotics. More recently, ARVs following an investment in the local manufacturing facility by the South African generic

³³² Ibid Chaudhuri at 7.

³³³ Losse K, Schneider E, and Spennemann C, (2007) 'The Viability of Local Pharmaceutical Production in Tanzania' GTZ, Eschborn. [Online] Available: <http://www2.gtzt.de/dokumente/bib/07-0300.pdf>

³³⁴ Ibid Chaudhuri 2014.

manufacturer Aspen which initially acquired 60 percent of Shelys share capital³³⁵ and later acquired the remaining shares.³³⁶ The completion of the new manufacturing facility in Tanzania allowed Shelys to double its production levels.³³⁷

In general however, the past several years have not been kind to local pharmaceutical manufacturers in Tanzania. Chaudhuri catalogues the closure or demise of several local companies in recent years. A case in point is that of Tanzania Pharmaceutical Industries (TPI) Limited, based in the northern Tanzanian town of Arusha. Initially founded in the 1970s by the Tanzanian government with support from the government of Finland, TPI ran into financial difficulties and ended up being shut down in the mid-1990s only to be privatized a few years later under the co-ownership of various Tanzanian entrepreneurs as well as Tanzanian Investment Funds. Since the mid-2000s, TPI had started producing three fixed-dose combinations ARVs³³⁸ with financial assistance from the EU ³³⁹ and with technical support from German NGO Action Medeor³⁴⁰ and know-how from scientist, Krisana Krasintu of Thailand who transferred the technology required to manufacture the ARVs to TPI.³⁴¹ In 2009, TPI was the second largest pharmaceutical company in Tanzania, accounting for 17 percent of the value of pharmaceutical production. A scandal around the production of falsified ARVs led to the cessation local ARV production by the TFDA. The Ministry of Health subsequently cleared TPI of any wrong-doing noting that the falsified medicines contained a counterfeit trademark of TPI's.³⁴²

³³⁵ See Press release '*Shelys Africa Limited*' dated 6 May 2008 [Online] Available:

http://www.aspenpharma.com/southafrica/hot/aspen_060508.htm

³³⁶ According to its website [Online] Available: <http://www.shelysafrica.com/>

³³⁷ East African Community Regional Pharmaceutical Manufacturing Plan of Action (EAC RPMPoA) 2011-2016 at 169.

³³⁸ The manufacturing of ARVs commenced with the manufacturing of lamivudine, stavudine and nevirapine, a commonly used first line treatment. Abacavir was added to the list of ARVs afterwards.

³³⁹ According information obtained from the presentation of Christine Häfele-Abah, Head of Quality Assurance, Action Medeor, during a presentation made at a conference on local pharmaceutical manufacturing in Africa, in Cape Town available at: http://www.localpharma-africa.info/ChristineHaele2_05-04-11.pdf, the EU had invested a grant of approximately 6.2 million Euros.

³⁴⁰ Ibid Mhamba and Mbirigenda who note that the partnership local manufacturing capacity building takes place through a contractual arrangement which specifies that ARVs produced will be made available to the public health sector at low cost for 40 months, after which the facility was to be handed over to TPI.

³⁴¹ Ibid Losse et al at 24.

³⁴² See for example, a newspaper article from the Tanzanian paper The Guardian of May 13 2013 entitled *Govt Clears Arusha firm in ARVs Scam* [Online] Available: <http://www.thecitizen.co.tz/News/Govt-clears-Arusha-firm-in-ARVs-scam/-/1840392/1850724/-/id8ljf/-/index.html>.

Chaudhuri (2014) at 3 cites a number of cases where local pharmaceutical producers have closed in the past few years. These include Keko which was established as early as 1968 and was as late as 2009, the third largest local

4.2.2 Challenges Facing Local Pharmaceutical Manufacturing: The Role of Industrial Policy and Intellectual Property Related Laws

While Tanzania's local pharmaceutical manufacturing industry, has received both foreign direct investment from the private sector and overseas development assistance, it remains modest and relatively fragile. In addition, local manufacturers face a number of challenges ranging from an insufficient number of qualified experts, unreliable infrastructure including an inconsistent supply of electricity, and high production costs.³⁴³

One of the largest challenges facing the local pharmaceutical manufacturing industry remains that of medicines quality. While ARVs manufactured by Shelys have complied with the GMP standards required by the TFDA, and have obtained marketing approval, no local company has as yet, managed to retain pre-qualification approval from the WHO or from the US FDA, which prevents either company from participating in GFATM or PRPFAR financed treatment programmes. This situation leaves Tanzanian manufacturers to compete for local or regional government tenders handled by the Tanzanian Medical Stores Department (MSD)³⁴⁴ which are miniscule in comparison to the level of funding available through the GFATM and PEPFAR.³⁴⁵ Attempts are underway to strengthen the technological capacity of local pharmaceutical manufacturers to be able to manufacture newer generation ARVs primarily through the investment in Shelys by Aspen Pharmacare. Shelys was the first local manufacturer to obtain WHO pre-qualification but lost that status. TPI had been intending to establish a WHO GMP compliant plant for ARVs, including second-line ARVs³⁴⁶ before the scandal concerning the falsification of ARVs

producer accounting for up to 15 percent market share. Other companies in recent years that have also ceased operations include Interchem and Tanzinsino.

³⁴³ Some of these challenges are discussed in more detail by Losse et al, Mhamba and Mbirigenda as well as Wilson Kinsley R, (2009).

³⁴⁴ The MSD is an autonomous government department affiliated to the Ministry of Health. Established by the Medical Stores Department Act 13 of 1993, it operates on a commercial, self-sustaining basis, with a governance structure separate from the Ministry of Health.

³⁴⁵ Given the increase in the number of patients requiring treatment, Tanzania's Ministry Health and Social Welfare increased its medicines budget from US\$ 6.6 million in 2003 to US\$ 98.7 million in 2008.

³⁴⁶ TPI is compliant with GMP standards imposed by the TFDA but not those of the WHO, whose prequalification standards generally requires a large investment in upgrading or building new facilities as well as financing for the lengthy application process. According to Wilson Kinsley at 147, WHO prequalification of products can take between 12 and 24 months and can cost a firm up to US\$200,000. Product dossiers submitted for pre-qualification must include

prompted its shut-down. In the meantime, the challenges around the ineligibility of the industry to compete for donor financed ARV tenders remain.

Another significant challenge facing local manufacturers remains the affordability of their products. No Tanzanian pharmaceutical manufacturers has the capacity to produce APIs, which leaves them at a price disadvantage to larger foreign companies from India and South Africa, who have the capacity to manufacture their own APIs. Aside from being a technologically sophisticated industry, API manufacturing can account for as much as 65 percent and 90 percent of the total costs of a pharmaceutical product.³⁴⁷ A study by the International Finance Corporation (IFC) in 2008 found for instance, that the cost of manufacturing a 100 unit container of analgesics, a basic painkiller, in Tanzania was 25 percent more than India and 15 percent more than South Africa.³⁴⁸ While it might have been hoped that local manufacturers would offset some production cost by not having to factor in transportation costs that foreign companies would have to, the same report found that freight costs comprise only 4 percent of the 25 percent production cost difference between Tanzanian manufacturers and Indian generic manufacturers.³⁴⁹

Traditionally, developing country governments offer fiscal incentives to local pharmaceutical companies to incentivise local production and Tanzania is no exception. The 1991 National Drug Policy lists among its aims:

“Promoting the national pharmaceutical industries (parastatal and private), with a view to become self-reliant in the formulation of drugs from imported raw materials”

clinical data and bioequivalence studies for fixed dose combinations and each individual pharmaceutical product. This requires not only the appropriate facility and equipment, but also the necessary trained human resources. The total development cost of a single oral dose was estimated by industry informants to be from US\$800,000 to US\$1 million, excluding any required plant modifications and labour costs. These costs increase if a more technologically complex second-line ARV is developed.

³⁴⁷ Pinheiro E, Antunes O, and Fortunak J, (2008) ‘A survey of the syntheses of active pharmaceutical ingredients for antiretroviral drug combinations critical to access in emerging nations.’ *US National Library of Medicine*, National Institute of Health 79 (3)143–165.

³⁴⁸ International Finance Corporation (2008) ‘The Business of Health in Africa: Partnering with the Private Sector to Improve People’s Lives’ IFC, World Bank Group, Washington DC [Online] Available: [http://www.ifc.org/ifcext/healthinafrica.nsf/AttachmentsByTitle/IFC_HealthinAfrica_Final/\\$FILE/IFC_HealthinAfrica_Final.pdf](http://www.ifc.org/ifcext/healthinafrica.nsf/AttachmentsByTitle/IFC_HealthinAfrica_Final/$FILE/IFC_HealthinAfrica_Final.pdf)

³⁴⁹ Ibid IFC at 78.

The policy also notes that its long term objective is to:

*“...support the gradual development of self-sufficiency in the production of intermediary and raw materials on such chemical entities, where Tanzania has a comparative advantage in production. Where feasible, regional joint production of both finished products and raw materials will be promoted.”*³⁵⁰

In discussing other incentives provided by the government to stimulate local production Chaudhuri³⁵¹ notes that there are no import duties on raw materials, components and machinery and no value added tax or excise for domestic formulations. Another significant policy is the 15 percent price advantage given to local manufacturers for procurements undertaken by the MSD of Tanzania.³⁵² While this is an important incentive, it does not negate the possibility of anti-competitive behaviour from larger foreign generic manufacturers, who may opt to engage in predatory pricing by tendering at marginal cost to win tenders and drive local producers out of the market. For Tanzanian policy makers, the tension between providing domestic support as part of Tanzania’s industrial policy objectives (in the form of preferential price advantages, and more direct subsidies) will have to be balanced with the urgent need to sustain and scale up national treatment programmes. It should be noted that while Tanzania is unlikely to become ineligible to receive funding from the GFATM in the short to medium term, multilateral funding mechanisms increasingly expect countries to co-finance their AIDS, TB and malaria responses.³⁵³

³⁵⁰ See WHO (2003) ‘A short Information Manual on the Tanzania National Drug Policy, The Master Plan for the Pharmaceutical Sector 1992-2000 Tanzania Mainland, A summary, Hospital Therapeutic Committees’ [Online] Available: <http://collections.infocollections.org/whocountry/en/d/Jh4335e/2.3.4.1.html#Jh4335e.2.3.4.1>

³⁵¹ 2007 at 18.

³⁵² Chaudhuri notes that the 15 percent is added to the cost plus freight price of international suppliers. That price is compared with the price quoted of local manufacturers, and the tender is awarded to the latter if its price is lower than or equal to the international supplier’s 15 percent mark-up.

³⁵³ A precursor of that is a recent move by the Global Fund in introducing counterpart financing where all countries who receive funding from the GFATM are required to commit a minimum share of funds to match funds provided through GFATM. As a low income country, Tanzania at this stage is only required to invest 5 percent of GFATM investment. This amount increases to 20 percent for lower-middle income countries, 40 percent for upper middle income countries and 60 percent for high income countries.

Given that the source of first-line ART continues to be Indian generic companies,³⁵⁴ the sustainability of treatment depends on the degree to which public health related TRIPS flexibilities discussed above are found in the relevant legislation of mainland Tanzania and Zanzibar. The remainder of this chapter will examine the extent to which public health related TRIPS flexibilities have been incorporated into the various laws of Tanzania and what further amendments might be required to retain the necessary intellectual property policy space. This includes a brief definition of the regulatory organisations concerned, which will follow next.

4.2.3 Drug regulatory authorities in Mainland Tanzania and Zanzibar: a Profile

(a) The Tanzania Food and Drugs Authority

The TFDA is a semi-autonomous body established in 2003 under the Ministry of Health, and Social Welfare,³⁵⁵ and is the drug regulatory authority responsible for controlling the quality, safety and efficacy of food, conventional and traditional medicines, cosmetics and medical devices in mainland Tanzania. Its activities are governed by the Tanzania Food, Drugs and Cosmetics Act³⁵⁶ and include the evaluation and the registration of pharmaceuticals ensuring that all products on the market have been licensed in accordance with the requirements of the relevant legislation, conducting regular inspections of manufacturers, retailers and wholesalers. With a staff of approximately 170 as of 2011,³⁵⁷ the TFDA is also responsible for the control of pharmaceutical imports in and exports out of mainland Tanzania and the constant monitoring of products on the market to ascertain their safety.

The second hypothesis advanced in chapter one of this thesis was that there are capacity constraints within the relevant government departments in eastern and southern Africa which hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and the

³⁵⁴ See WHO global price reporting mechanism website [Online] Available: <http://apps.who.int/hiv/amds/price/hdd/> See also, Waning, B et al (2010) which found that more than 80 percent of adult ARVs and up to 90 percent of paediatric ARVs used in developing countries originate from India.

³⁵⁵ Additional information on the functions and scope of the TFDA is available on its website: <http://www.tfda.or.tz/function.php>

³⁵⁶ No. 1 of 2003.

³⁵⁷ WHO (2011) *Pharmaceutical Sector Country Profile Questionnaire: United Republic of Tanzania*. <http://apps.who.int/medicinedocs/en/m/abstract/Js19870en/>

use of these flexibilities when needed. The challenges around capacity in Tanzania extend beyond the integration of flexibilities in national legislation and in some instances impede the ability of the TFDA to undertake its regulatory functions and effectively perform its statutory functions, particularly that relating to the compliance of pharmaceutical products with local GMP standards. A number of manufacturers produce pharmaceutical products affordable to most Tanzanians, but not in accordance with GMP. Chaudhuri cites at least one example of a large, reputable Indian pharmaceutical company having withdrawn from the Tanzanian market on the basis that the TFDA was unable to prevent the sale of sub-standard or falsified pharmaceuticals in the market.³⁵⁸ Other large companies like Cipla and Ranbaxy have adopted strategies such as product branding to distinguish their products from potentially sub-standard or falsified medicines.³⁵⁹

In recent years, the Ministry of Health has adopted some innovative measures to address the challenge of sub-standard medicines. For instance, the Ministry of Health developed a database of unregistered medicines and used it to check the sales of certain pharmaceutical products at various outlets. Inspectors invited pharmacies found to be selling unregulated medicines to co-operate with the authorities' efforts to track the source of such products. Those who refused faced well-publicized closures.³⁶⁰ In 2010, the TFDA's quality control laboratory was accorded the status of a WHO prequalified laboratory; one of a handful of quality control laboratories in Africa to be awarded this status by the WHO.³⁶¹

The TFDA has a history of working closely with and being largely supportive of the local pharmaceutical manufacturing industry and has assisted several companies to phase in national GMP standards. It regularly provides local pharmaceutical manufacturers with guidelines relating to the construction of manufacturing plants and the packaging of products, and gives local producers a slight pricing advantage by charging them slightly lower registration fees in

³⁵⁸ Ibid Chaudhuri (2014) at 15.

³⁵⁹ Ibid.

³⁶⁰ Refer to: See http://www.msh.org/seam/country_programs/3.1.4b.htm#top as cited in Oxfam (2011) 'Eye on the ball: Medicines Regulation- not IP Enforcement can best Deliver Quality Medicines' Briefing paper 143 [Online] Available: <https://www.oxfam.org/sites/www.oxfam.org/files/eye-on-the-ball-medicine-regulation-020211-en.pdf>

³⁶¹ See the 28th edition of Prequalification programme, December 2009 [Online] Available: http://apps.who.int/prequal/lists/PQ_QCLabsList.pdf

comparison to foreign pharmaceutical companies, who are also required to pay a 2 percent tax on the value of imports into mainland Tanzania, that local companies are exempted from.³⁶²

b) Zanzibar Food and Drugs Board

The Zanzibar Food and Drugs Act ³⁶³established the Food and Drugs Board in 2007 as a semi-autonomous structure under the Ministry of Health for the registration of medicines and to control the quality control of health technologies in the territory. The Zanzibar Food, Drugs and Cosmetics Board (ZFDB) is established, and depends on a separate government laboratory facility for drug quality control. In addition to the Act, a National Drug Policy³⁶⁴ regulates pharmaceutical products in Zanzibar. The capacity constraints facing drug regulatory authorities in Zanzibar are more acute than those in Mainland Tanzania. For instance, registration of pharmaceuticals is only partly done in Zanzibar because there are insufficient registration facilities and an insufficient number of qualified personnel. This exposes the market in Zanzibar to the infiltration of sub-standard and counterfeit products.³⁶⁵ As a safeguard, the ZFDB which had a staff of 63 employees as of the end of 2011, rubber-stamps the approval of many of the pharmaceutical products registered by the TFDA in mainland Tanzania. Aside from product registration, several of the elements required to maintain assure the quality of pharmaceuticals are missing in Zanzibar. According to the National Drug Policy:

“The laboratory capacity to test products is currently limited by the severe financial constraints and inadequate skilled human resources. Currently laboratory testing of pharmaceutical products are carried out by using Mini lab kit. Conditions for distribution and storage of medicines are often inadequate leading to premature deterioration and waste of sensitive items. Post-marketing surveillance capacity is strictly limited by human resources and logistical constraints.”

The second hypothesis advanced in chapter one pertaining to the capacity constraints facing national institutions in mainland Tanzania and Zanzibar will be further tested below.

³⁶² Ibid Wilson Kinsley, at 139.

³⁶³ No.2 of 2006.

³⁶⁴ Zanzibar National Drug Policy, on file with author.

³⁶⁵ Zanzibar National Drug Policy page 15.

4.3 Tanzania's Industrial Property and Related Legislation and Institutions: To What Extent are TRIPS Flexibilities Reflected and Implemented?

4.3.1 A brief Background of Intellectual Property Legislation in Tanzania and of Relevant Institutions

Intellectual property law has a long history in Tanzania dating back decades before independence. The formal introduction of intellectual property laws in eastern and southern Africa was initiated by European colonial powers in the late nineteenth century, after the 1884 Congress of Berlin.³⁶⁶ In the case of Tanganyika, the first patent law, the Patents (Registration) Ordinance was promulgated in 1931. The Ordinance, modelled after the British Patents, Designs and Trade Marks Act of 1883, was directly linked with the UK patent system.³⁶⁷ In a move meant to extend the rights of British inventors to colonial territories, a patent granted in the UK would be automatically valid for registration in Tanganyika. Conversely, any inventor or innovator based in Tanganyika was compelled to file a patent application in the UK to have a patent registered in Tanganyika.³⁶⁸ This relationship with the UK patent law was kept with the passing of the Patent (Registration) Ordinance (Chapter 217 of Tanganyika, passed after independence in 1962, and was only removed with the passing of the Patent Act of 1987,³⁶⁹ cited as a motivating factor behind the enactment of new legislation.³⁷⁰

In addition to the Patent Act which is applicable in mainland Tanzania, a recently adopted industrial property Act is in force in Zanzibar. As will be discussed below, significant capacity constraints have affected the effective operation of both pieces of legislation.

³⁶⁶ Deere C, (2008) at 35.

³⁶⁷ Mwalimu U, (2003) 'The Implications of WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) on Tanzania: A focus on pharmaceuticals, Working Paper Series no. 4, Economic and Social Research Foundation (ESRF), Dar es Salaam, at 12. [Online] Available: http://www.esrf.or.tz/global/output/WPS04_Mwalimu_TRIPS.pdf

³⁶⁸ Ibid Mwalimu at 12.

³⁶⁹ Act 1 of 1987 as amended by Acts 13 and 18 of 1991.

³⁷⁰ Ibid Mwalimu at 13. The second reason cited was the adoption of a science and technology policy in 1986, which anticipated the promotion of innovation for the facilitation of technology transfer through, *inter alia*, the grant and regulation of patents.

The Patent Act applicable to mainland Tanzania is administered through the Business Registration and Licensing Agency (BRELA), the semi-autonomous government agency charged with the administration and implementation of laws and regulations relating to intellectual property among other functions.³⁷¹ BRELA operates with significant human resource constraints. While 62 staff members were employed at BRELA, in 2012, only 10 worked in the Industrial Property Division of which one had pursued an advanced degree specialising in intellectual property. The other institution with a mandate and capacity to administer industrial property including patents relating to science and technology is the Tanzanian Commission for Science and Technology (COSTECH)³⁷² which drafts patent documents, files patent applications and undertakes patent searches. As of 2012, COSTECH's capacity on intellectual property matters was limited with only one employee having a post-graduate degree with a specialisation in intellectual property. Neither institution currently undertakes substantive patent examinations, relying instead on the ARIPO Secretariat to undertake this important function. The implications of the enabling ARIPO instruments and examining procedures on treatment access in Tanzania and other countries in the region are discussed in more detail in chapter six.

Mainland Tanzania has been in the process of patent law reform for several years dating back to at least 2006.³⁷³ A number of initiatives by various UN, inter-governmental and foreign Aid agencies to support the amendment of industrial property legislation in mainland Tanzania³⁷⁴ have

³⁷¹ BRELA's divisions include those tasked with the implementation of Administrative law, Commercial law, Intellectual Property (headed by a Deputy Registrar) and Industrial Licensing Division (headed by a Deputy Registrar).

³⁷² COSTECH was established by Parliament by Act 7 of 1986 and is a parastatal responsible for the co-ordinating and promoting research and technology development activities in Tanzania, and is tasked specifically with facilitating national, regional and international cooperation in scientific research and technology development and transfer.

³⁷³ A draft copy of an Industrial Property Act for Mainland Tanzania as prepared by WIPO in 2006 is on file with the author.

³⁷⁴ From 24-28 July 2006 for instance, a workshop was organized by UNDP, TWN and the WHO to incorporate more public health related TRIPS flexibilities into the draft Industrial Property Act. According to the then Chief Executive Officer of BRELA, Mr. E. Mahingila, there was a need for mainland Tanzania as an LDC to amend its industrial property legislation to take advantage of the LDC exemption available to WTO Members. In December 2007, UNDP and the EAC organised a meeting in Arusha Tanzania to disseminate the findings of a study on how intellectual property legislation in the individual EAC countries could be amended to incorporate TRIPS flexibilities and to facilitate pooled procurement of essential medicines. Also in 2007, the German technical agency GTZ released a study on local pharmaceutical production in Tanzania which also contained recommendations on the amendment of patent legislation. In 2008, the EAC held a workshop in Arusha, Tanzania, for trade and pharmaceutical experts in its Partner States on the "Review of Essential Medicines Related Patent Laws and WTO TRIPS Flexibilities" [Online] Available: http://www.unctad.org/sections/dite_totip/docs/tot_ip_0005_en.pdf

taken place over the past few years. It is highly unlikely that the advice provided to officials from BRELA and other institutions has been uniform in nature,³⁷⁵ given the variety of entities with different perspectives on intellectual property have provided mainland Tanzania with technical assistance on various aspects of its industrial property legislation in recent years.³⁷⁶ A number of years after the review of the industrial property law reform commenced, Tanzania submitted a request to WIPO to assist with the development of an IP strategy.³⁷⁷ Work on the draft industrial property Act has been suspended pending the development of an IP strategy.³⁷⁸

The capacity constraints facing BRELA support the second hypothesis advanced in chapter one of this thesis, namely that capacity constraints within the relevant government departments in eastern and southern Africa hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and their use when needed. A 2012 draft National IP strategy prepared by WIPO also identifies limited capacity constraints within BRELA and as well as an incoherent approach to intellectual property administration.³⁷⁹ Mainland Tanzania also has a Fair Competition Act administered by the Ministry of Industry and Trade, which has a number of provisions that could be used to prevent anti-competitive behaviour by originator or generic manufacturers. Thus far, however, it appears that the competition Act has only been used by brand name manufacturers of goods to prevent the introduction of products with counterfeit trademarks from entering the local market.³⁸⁰

Several workshops have also been held by WIPO on a broad range of intellectual property matters, some of which are listed on the WIPO website [Online] Available:

http://www.wipo.int/meetings/en/archive_meeting.jsp?meeting_country=176

³⁷⁵ Musungu S, (2005) 'Rethinking innovation, development, and intellectual property in the UN: WIPO and Beyond' TRIPS Issue Paper 5, QUNO, Geneva at 27, lists several UN agencies whose mandate touches on intellectual property. These include, Specialised Agencies such as the international Labour Organisation (ILO), Food and Agricultural Organisation (FAO), United Nations Economic Social and Cultural Organisation (UNESCO), International Telecommunications Union (ITU), UNIDO, UNCTAD, UNEP, UNDP and others. Other key providers of technical assistance include WIPO and the WTO. There are also several developed countries who provide technical assistance to LMICs on intellectual property related matters including the US, EU, Japan, Canada, Australia, and Germany.

³⁷⁶ Ibid Matthews (2005) who notes that some of the technical advice and capacity building activities in developing countries may not necessarily be tailored to meet the national policy objectives.

³⁷⁷ A draft Strategy developed by a WIPO consultant is [Online] Available: <http://www.brela-tz.org/htmls/NIPS-1.pdf>

³⁷⁸ According to an official from BRELA.

³⁷⁹ WIPO (2012) at 13 and 23.

³⁸⁰ The US government has been providing technical assistance to competition authorities in Tanzania in this regard with a number of trainings to local officials on how intellectual property enforcement can be enhanced through the use of competition law. See for example, Kisyombe M, (2012) 'Emerging Issues in Consumer Protection:

As is the case with drug regulatory institutions and legislation, the adoption of its Constitution³⁸¹ has spurred authorities in Zanzibar on to enact copyright³⁸² and industrial property legislation.³⁸³ As will be discussed in more detail below, Zanzibar's enactment of a new Industrial Property Act in 2008 has allowed it to incorporate significantly more public health related TRIPS flexibilities into its national legislation. The Act is administered by the Registrar General's Office in Zanzibar, which is also responsible for the registration and issuance of certificates of vital events, companies and business names as well as trademarks and patents. The Registrar General's office has limited capacity with regards the administration of industrial property and relies on ARIPO and WIPO for capacity development activities.³⁸⁴

The extent to which public health related TRIPS flexibilities are found in the mainland Tanzania's Patent Act as well as Zanzibar's Industrial Property Act will be discussed below. In the case of mainland Tanzania, the law does not incorporate a number of public health related TRIPS flexibilities given that there has been no significant revision of the law since the WTO was established. Tanzania has also ratified the WIPO Convention³⁸⁵ and the Patent Cooperation Treaty (PCT)³⁸⁶ and is a Member State ARIPO, having ratified the Agreement on the Creation of ARIPO in October 1983. The next section contains a detailed analysis of mainland Tanzania and Zanzibar's current patent and industrial property legislation and the degree to which it reflects the flexibilities embodied in the TRIPS Agreement.

Complementarities and areas of tension', Paper given at UNCTAD Expert Group on the Interface between competition policy and consumer welfare [Online] Available: http://unctad.org/meetings/en/Presentation/ciclp2012_EMCP_S3_Kisyombe_Discussion_en.pdf

³⁸¹ Constitution of the Revolutionary Government of Zanzibar was adopted in 1984 and subsequently amended in 1990, 1992 and 2002.

³⁸² Copyright Act 14 of 2003.

³⁸³ Industrial Property Act 4 of 2008.

³⁸⁴ A 2007 draft of the Industrial Property Bill prepared for the Registrar General by WIPO is on file with the author. The draft contains a number of TRIPS plus elements and had not incorporated many of the public health related flexibilities which were eventually integrated into the Act after two workshops in 2007 organized by UNDP and TWN.

³⁸⁵ Applicable in Tanzania since 30 December 1983.

³⁸⁶ Applicable since 14 September 1999.

4.3.2 Tanzania's Intellectual Property and Related Legislation: To What Extent are Public Health Related TRIPS Flexibilities Reflected?

This section contains an extensive discussion on the most beneficial policy for mainland Tanzania would examine the extent to which the following flexibilities in the TRIPS Agreement have been incorporated into Mainland Tanzania's Patent Act.

(a) Transition periods

Article 65 of the TRIPS Agreement provides exemption periods exempting WTO Members from complying with the TRIPS Agreement upon accession to the WTO³⁸⁷ while Article 66 exempted LDC Members of the WTO from having to comply with the TRIPS Agreement with the exception of Articles 3,4 and 5 for a 10 year period which ended in 1 January 2006.³⁸⁸ The LDC waiver was extended in November 2005³⁸⁹ until 1 July 2013 and further extended in June 2013 to 1 July 2021.³⁹⁰ In addition to these waivers which exempt LDCs from intellectual property obligations, WTO Members also agreed to grant a waiver specific to pharmaceutical products in paragraph 7 of the Doha Declaration until 1 January 2016, subject to further extension. The potential importance of these waivers for Tanzania can't be overstated, as they allow countries to control the circumstances under which pharmaceutical patents can be granted and to some degree, revoked, thus facilitating generic competition.³⁹¹

The consequences of the debate over whether LDCs may suspend existing patents for pharmaceutical products that were already granted, is diminished by the fact that generic competition predominantly from Indian generic manufacturers has resulted in extremely

³⁸⁷ Article 65.1 obliges developed countries to comply with the TRIPS Agreement within a year of joining WTO, while Article 65.2 and 65.3 entitled developing country Members and economies in transition to delay the implementing the TRIPS Agreement for a five year period from accession to WTO. Article 65.4 provides developing countries obliged to extend product patent protection to areas of technology not so protectable in its territory before joining the WTO with an additional five year exemption period. The latter expired for all developing countries that joined the WTO in 1995.

³⁸⁸ Except as regards the obligation to respect the basic non-discrimination principles of national treatment and most-favoured nation treatment contained in Articles 3, 4 and 5.

³⁸⁹ As per WTO document IP/C/40.

³⁹⁰ See WTO document IP/C/64.

³⁹¹ The latest waiver does not contain a "no roll back clause" which was present in the 2005 waiver, which effectively prevented LDCs from rolling back the levels IP protection to meet specific domestic policy objectives.

competitive pricing of first line ARVs in Tanzania in recent years.³⁹² However, mainland Tanzania may wish to make use of the LDC waiver to regulate the patenting of newer generation ARVs³⁹³ and those still in the innovation pipeline where competition from generic manufactures is likely to be more limited than in the past because of increased patenting of originator products in India and in other countries with significant pharmaceutical manufacturing capacity.

While this important flexibility has been available for almost two decades, mainland Tanzania's Patent Act still provides for the patenting of both pharmaceutical products and processes.³⁹⁴ Spennemann,³⁹⁵ in debating whether the decision by an LDC like Tanzania to take advantage of the LDC waiver would have any positive implication in stimulating innovation and local pharmaceutical production, notes that:

“From a policy perspective, it is questionable whether the non-enforcement of existing IPRs is an appropriate way of promoting local production of pharmaceuticals. Tanzanian firms intending to manufacture medicaments against HIV or tropical diseases will in any case need to rely on the importation of a number of pharmaceutical ingredients and thus collaboration with foreign patent holders. Such collaboration, normally through the negotiation of voluntary licenses, will not be encouraged if foreign investors see their vested rights not enforced.”

The larger question is whether a sufficiently sophisticated pharmaceutical manufacturing industry in Tanzania can be foreseen in the future, which might merit a decision by the government to use intellectual property protection as a means to incentivise foreign direct investment by originator companies, to develop the domestic industry. Several authors have extensively discussed the

³⁹² A spreadsheet for instance from the WHO Global Price Reporting Mechanism (GRPM) of 2013 shows that the WHO recommended first-line treatment FDC of efavirenz, tenofovir and emtricitabine was available at a median price of US\$ 157 per patient per year.

³⁹³ According to the GPRM, the cost of medicines used in third-line treatment regimens is still extremely expensive even in LDCs like Tanzania. According to the database, in 2013, darunavir was sold at US\$ 2,667 per patient per year, while etravirine cost US\$ 359 per patient per year and raltegravir, cost US\$ 553 per patient per year amounting to a total of more than US\$ 3500 per patient per year.

³⁹⁴ Section 7(1) of the Act notes that:

“ For the purposes of this Act, "invention" means a solution to a specific problem in the field of technology and may relate to a product or process”

Section 7(2) which lists a number of exemptions to Section 7(1) does not include pharmaceutical products or processes.

³⁹⁵ UNCTAD (2006) ‘Intellectual Property Rights, Investment and Access to Medicines: the United Republic of Tanzania’ UNCTAD Secretariat Geneva (on file with author).

factors which determine the success of technology transfer agreements in the pharmaceutical industry.³⁹⁶ As Maskus³⁹⁷ notes:

“The various means by which IPRs influence FDI are subtle and complex. Moreover, it must be emphasized that strong IPRs alone are insufficient for generating strong incentives for firms to invest in a country. If that were the case, recent FDI flows to developing economies would have gone largely to sub-Saharan Africa and Eastern Europe. In contrast, China, Brazil, and other high growth, large-market developing economies with weak protection would not have attracted nearly as much FDI if investment were heavily dependent solely on IPRs.”

Other factors that should influence impact on a policy adopted by authorities in Tanzania include the government’s longer term industrial policy objectives, fiscal policy, investment regulations, production incentives, trade policies, and competition rules.³⁹⁸ Given that at present, very few companies in Tanzania locally produce ARVs, and that the largest one, Shelys is entirely owned by a foreign investor, it follows that the adoption of an intellectual property regulation that facilitates imitation rather than innovation would be more advantageous to mainland Tanzania. This rationale is reinforced by developments in the region such as the investment of the Indian manufacturer Cipla in a Ugandan generic company, Quality Chemicals,³⁹⁹ and in co-operation with the East African Community’s plans to harmonize intellectual property legislation among its Partner States to facilitate regional co-operation on pharmaceutical products. The implications of not using the LDC waiver are that local generic pharmaceutical manufacturers would be required to determine the patent status of APIs and attempt to negotiate voluntary licenses for health

³⁹⁶ See for instance, Correa C, (2005). “Can the TRIPS Agreement Foster Technology Transfer to Developing Countries?” in Maskus K, and Reichman J, (Eds.), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*. Cambridge: Cambridge University Press. See also Moon S, (2008) ‘Does TRIPS Art. 66.2 Encourage Technology Transfer to LDCs? An Analysis of Country Submissions to the TRIPS Council (1999-2007) Policy Brief No 2, UNCTAD- ICTSD Project on IPRs and Sustainable Development. Geneva.

³⁹⁷ Maskus K, (1997) ‘The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer’ *Duke Journal of Comparative and International Law*, 109-161, at 128-129.

³⁹⁸ *Ibid* Maskus at 129.

³⁹⁹ According to the Quality Chemicals website, upon request by the Government of Uganda, Cipla agreed to extend technical assistance to Uganda through a joint venture with a local partner Quality Chemicals Ltd to enable Uganda locally manufacture ARVs and anti-malarial drugs under Cipla brand names. In January 2010, the WHO prequalified the facility as a contract manufacturing plant for Cipla, India. As of 2013, Quality Chemicals portfolio of ARVs included zidovudine, lamivudine, nevirapine and efavirenz, with the latest FDCs approved by the WHO scheduled for local production shortly. [Online] Available:

http://www.qcpl.co.ug/index.php?option=com_k2&view=item&layout=item&id=12&Itemid=62

technologies on which patents exist, failing which, a request for a compulsory license could be made to the relevant authorities.

Another challenge that would be negated by the adoption of the LDC exemption is the challenge of how to ascertain the patent status of key ARVs as discussed above in chapter three. It remains a challenge to easily and accurately determine the patent status of key ARVs in several countries in east and southern Africa, including Tanzania as illustrated by the unnecessary compulsory licenses issued by authorities in Zambia in 2004. While the MPP database has played an important role in alleviating the most difficult challenges in obtaining relevant patent information, the database is not always current. Information is periodically updated from the relevant patent offices and may become outdated.⁴⁰⁰

As may be expected, given its more recent enactment, Zanzibar's Industrial Property Act makes more effective use of the transition periods. The Act excludes new uses patents of known forms of products and processes, including pharmaceuticals patents.⁴⁰¹ It also explicitly excludes⁴⁰² the patenting of inventions necessary to protect human, animal or plant life and or health, which may be interpreted to include pharmaceutical patents. Importantly, the Act⁴⁰³ explicitly excludes pharmaceutical products and processes from patentability until 1 January 2016 or such time as subsequently agreed by the WTO Council for TRIPS.

The exclusion of pharmaceutical patents from patentability is supplemented by a provision providing a transition period for the protection of pharmaceutical test data, the latter to apply only when pharmaceutical patents eventually are granted in Zanzibar.⁴⁰⁴ As there is no local pharmaceutical industry in Zanzibar,⁴⁰⁵ and there are no plans to develop one in the foreseeable future, the inclusion of a transition period into Zanzibar's legislation is a pro-public health

⁴⁰⁰ In the case of ARIPO, the latest updates occurred in November 2013.

⁴⁰¹ Section 3(1)(v).

⁴⁰² Section 3(1)(ix).

⁴⁰³ Section 3(1)(x).

⁴⁰⁴ Section 75(5)(h) reads as follows:

“undisclosed test data and other data relating to pharmaceutical products shall be protected in Zanzibar in accordance with (a) to (g) of this sub-section, after 1 January 2016, or such period of extension agreed upon by the World Trade Organization Council for TRIPS, this paragraph shall apply to marketing approval requests that will be pending on that date as well as to those filed on or after that date.

⁴⁰⁵ As confirmed by the Zanzibar Drug policy.

measure, the effectiveness of which may have been reduced by the adoption of a section on the protection of pharmaceutical test data, as discussed below. Authorities in Zanzibar have also included a provision⁴⁰⁶ establishing a patent mailbox upon expiry of the transition period as provided for under Article 70.8 of the TRIPS Agreement.⁴⁰⁷ The implications of a patent mailbox for Zanzibar may be minimal in practice, as the Registrar General's office relies on ARIPO to conduct pharmaceutical patent examinations. In addition, scholars have asserted⁴⁰⁸ that the wording of Article 70.8 of TRIPS which requires the establishment of a mailbox is only applicable to those countries who did not provide patent protection as of the date of entry into force of the TRIPS Agreement. By virtue of legislation which was replaced in 2008,⁴⁰⁹ Zanzibar had provided for pharmaceutical and agricultural chemical patents, provided they were filed in the UK. The question therefore, is whether the authorities in Zanzibar did not need to establish a patent mailbox system, or to grant exclusive marketing rights as required by Article 70.9 of TRIPS,⁴¹⁰ and whether the mailbox can be revoked.

(b) Patent Opposition and Revocations

While the TRIPS Agreement does not directly regulate the issue of patent oppositions, a number of countries⁴¹¹ provide an opportunity for parties to oppose the granting of a patent or to request

⁴⁰⁶ According to the relevant portion of Section 10(8):

“...immediately after the commencement of this Act, with regard to pharmaceutical products and process, the Industrial Property Office shall receive patent applications and shall maintain such applications pending their application as of 1st January 2016, or such period of extension agreed upon by the World Trade Organization Council for TRIPS.”

⁴⁰⁷ The requirement that developing countries implement a patent mailbox was affirmed in the WTO Appellate Body Report of, India–Patent Protection for Pharmaceutical and Agricultural Chemical Products, (WT/DS50/AB/R, 1997). In confirming its interpretation of the mailbox, the Appellate Body found that India did not provide mailbox and exclusive marketing rights for foreign holders of pharmaceutical and agricultural chemical product patents, as required by Article 70.8 and 70.9 respectively.

⁴⁰⁸ Correa C, (2002) ‘Implications of the Doha Declaration on the TRIPS Agreement and public health’, World Health Organization, Health Economics and Drugs Series, No 12.

⁴⁰⁹ Cap 157 of 1932.

⁴¹⁰ Article 70.9 reads:

“Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.”

⁴¹¹ See for instance, Section 25 of the Indian Patents Amendment Act of 2005, which lists several grounds for the invalidation of a patent including: wrongfully obtaining the invention; evidence of a prior claim in the country; prior public knowledge or public use in India; obviousness and lack of inventive step; not qualifying as an invention under the Act; or insufficient description of the invention

its invalidation by filing an opposition with the competent government authority. While a study conducted by the US Federal Trade Commission in 2002 found that in 104 patent litigation cases determined by US Courts, generic companies prevailed in 73 percent of cases,⁴¹² patent litigation can be lengthy and costs on average, almost 62 percent more expensive than other forms of civil litigation in the US.⁴¹³ Furthermore, relying on generic companies to litigate is unlikely to be an effective solution for an LDC like Tanzania, where because only a handful of local pharmaceutical companies, of comparatively modest means even have the capacity to manufacture ARVs.

Countries have the flexibility to provide for patent opposition or revocation proceedings before or after the grant of a patent.⁴¹⁴ According to Kapczynski,⁴¹⁵ countries with high levels of patent protection have traditionally preferred post-grant oppositions or have removed the possibility of patent oppositions on substantive grounds altogether. Despite this trend, scholars note that pre-grant oppositions are more likely to result in invalidation of questionable patents than post-grant patent oppositions.⁴¹⁶

In recent years, there has been a proliferation of pre-grant patent oppositions and revocation proceedings filed by treatment activist or consumer groups, in India, Thailand and Brazil. In Thailand in 2001, treatment activists filed a post-grant opposition in the Thai Central Intellectual Property and International Trade Court⁴¹⁷ against a patent granted by the Thai intellectual property office to the originator company BMS for the ARV didanosine. The legal challenge was grounded in the premise that the patent on didanosine included an unlawful amendment that effectively

⁴¹² See US Federal Trade Commission (2002) ‘*Generic Drugs Entry Prior to Patent Expiration: An FTC Study*’ pages 12-14 [Online] Available: <http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>

⁴¹³ See Lee E, and Willging T, (2010), *Litigation Costs in Civil Cases: Multivariate Analysis* 8 (Federal Judicial Center). Reasons for the higher cost of patent litigation given include the large amount of money under dispute, electronic discovery requests, greater case complexity and the involvement of large law firms.

⁴¹⁴ India’s Patents Amendment Act of 2005 provides a third opportunity for a patent to be revoked, authorising opposition proceedings that may be initiated before the Intellectual Property Appeal Board or via a counterclaim in an infringement suit.

⁴¹⁵ Kapczynski A, (2009) ‘Harmonization and its Discontents: A Case Study of TRIPS Implementation in India’s Pharmaceutical Sector’, *California Law Review*, Vol. 97, p 1571 at 1598. Kapczynski notes that for instance, Germany and Japan abandoned pre-grant systems for post-grant systems in 1981 and 1994 respectively. See also Kesan J, (2002) ‘Carrots and Sticks to Create a Better Patent System’, *Berkeley Tech. L.J.* Vol 17, 763 at 781–82.

⁴¹⁶ For example, Kesan at 777, notes that pre-grant oppositions may also be more favourably viewed by the patent office as the patent office would not be forced to reverse a decision to grant a patent.

⁴¹⁷ *AIDS Access Foundation et al. v. Bristol Myers-Squibb Company and Department of Intellectual Property*, Central Intellectual Property and International Trade Court, Black Case No. Tor Por 34/2544, Red Case No. 92/2545 (2002)

broadened the scope of the patent over all dosage strengths. The Court found that BMS had attempted to assert exclusive ownership of the ARV beyond the dosage range originally specified in the patent registration, by deleting the limiting phrase “from about 5–100 mg per dose” from its patent claim.⁴¹⁸ This ruling led to another challenge against the patent on the grounds, inter alia, that, the requirement of novelty had not been met as the ARV had been available on the market before the patent was granted to BMS. The dispute was eventually settled with BMS choosing to “dedicate” the patent to the people of Thailand rather than risk a negative precedent.⁴¹⁹

The provision in India’s 2005 patent legislation authorizing patent oppositions is broadly worded, and authorizes “any person” including generic companies, patient groups or other members of civil society. Kapczynski identified as many as 200 pre-grant patent oppositions that had been filed in India’s patent offices between 2005 and mid-2007. A large number of oppositions were filed on the basis that the patent application does not meet the criteria required by Section 3(d) of the India Patents Act. Brazil’s intellectual property legislation⁴²⁰ enables third parties to make observations regarding the examination of patents. On this basis, patent authorities have seen a small number of pre-grant patent oppositions filed by treatment advocates on important ARVs including successful a mid-2008 opposition of the tenofovir disoproxil fumarate patent, filed by the originator pharmaceutical company Gilead⁴²¹ following a successful challenge in India by treatment activists in 2006. Gilead’s patent application was rejected by the Brazilian Patent office (INPI) in September 2008,⁴²² with a confirmation of the decision in June 2009.⁴²³ Wide ranging pre-grant and post-grant patent opposition proceedings could provide a country like Tanzania with

⁴¹⁸ A more detailed summary of the case and the findings by the Court is available at UNAIDS, (2006) ‘Thailand: people living with HIV challenge company's patent on antiretroviral drug. In *Courting Rights: Case Studies in Litigating the Human Rights of People Living with HIV*. Geneva, 92-94.

⁴¹⁹ See Wibulpolprasert S, Chokeyivat V, Oh C, and Yamabhai I, (2011) ‘*Government use licenses in Thailand: The power of evidence, civil movement and political leadership*.’ *Globalization and Health* 2011, 7:32 [Online] Available: <http://www.globalizationandhealth.com/content/7/1/32>

⁴²⁰ Law 9279 of 1996.

⁴²¹ The opposition against the tenofovir patent opposition was filed in June 2008 by the Brazilian Aids Advocacy Group ABIA (Brazilian inter-disciplinary Aids Association) as documented by a press Release issued by MSF [Online] at: <http://www.msfastaccess.org/content/abia-and-sahara-joint-press-release-patent-opposition-tenofovir>. The

⁴²² See MSF Press Release ‘*Brazil Rejects Patent on an Essential Medicine*’, of 2 September 2008, [Online] available: <http://www.doctorswithoutborders.org/press/release.cfm?id=3067>

⁴²³ However, Article 26 of law 9279/96 allows the patent applicant to make divisional patent applications before a final ruling from the patent office, which Gilead did, through the filing of a divisional application on 31 March 2009, leading to a final rejection of the divisional patent in May 2011.

an important opportunity to reduce ever-greening, thereby increasing the likelihood of obtaining affordable treatment for newer generation ARVs.

While Section 63 of mainland Tanzania's Patent Act⁴²⁴ provides for post-grant patent opposition, there is no provision for pre-grant oppositions. This is a significant omission, given the potential role of treatment activists and civil society groups in a number of LMICs,⁴²⁵ the increasing influence of national and regional treatment groups within the EAC such as the recent successful challenge of the 2008 Kenyan Anti-Counterfeit Act by treatment activists⁴²⁶ as well as efforts by Ugandan treatment activists to advocate for further inclusion of public health related TRIPS flexibilities into draft Industrial Property Legislation.⁴²⁷ Zanzibar's Industrial Property Act on the other hand provides for pre-grant patent oppositions⁴²⁸ but is silent on post-grant oppositions. As both mainland Tanzania and Zanzibar rely on the ARIPO Secretariat to examine pharmaceutical patents applications,⁴²⁹ provisions providing for pre-grant patent oppositions through the Harare Protocol may be of more consequence than at the national level.

(c) Patentability Criteria and Exclusions from Patentability

With the exception of the transition period available to LDCs, the most impactful pre-grant TRIPS flexibility available to WTO Members who are net importers of pharmaceutical technologies, must be Article 27 of the TRIPS Agreement which articulates the criteria for patentability and contains

⁴²⁴ Section 63(1) reads as follows:

"Any interested person, may, in proceeding instituted by him against the owner of a patent or in proceedings instituted against him by the said owner, request the court to invalidate the patent."

⁴²⁵ See for instance, a discussion of how treatment activists in South Africa, India and Brazil used the premise of access to medicines being a human right to assert the right to health in various intellectual property disputes, see Matthews D, (2011) 'Where Framing Meets Law: Using Human Rights as a Practical Instrument to Facilitate Access to Medicines in Developing Countries', The WIPO Journal, Thompson Reuters, Volume 3, Issue 1 at 113 [Online] Available: http://www.wipo.int/about-wipo/en/wipo_journal/pdf/wipo_journal_3_1.pdf

⁴²⁶ *Patricia Asero Ochieng and 2 others v. the Attorney General and Another.*

⁴²⁷ For instance, in late 2011, a letter, on file with the author, was written to the Ministry of Justice and Constitutional Affairs by the Center for Health, Human Rights and Development (CEHURD) with specific proposals to incorporate public health related TRIPS Flexibilities into the draft Industrial Property Bill 5 of 2009.

⁴²⁸ Under Section 10(7)(a).

⁴²⁹ According to Section 1 of the Harare Protocol:

"The African Regional Intellectual Property Organization (ARIPO) is empowered to grant patents and to register utility models and industrial designs and to administer such patents, utility models and industrial designs on behalf of Contracting States in accordance with the provisions of the Protocol, through its Secretariat..."

a list of subject matter that WTO Members may exclude from patentability. According to Article 27.1:

“Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

Article 27.1 does not provide any further guidance on how the patentability criteria should be applied. As Correa notes, if a country adopts a low standard of novelty, a lower bar for what constitutes an inventive step, and broadens the concept of utility or what can be classified as industrially applicable, the likelihood of a patent office granting a higher number of patent applications increases.⁴³⁰ As the discussion in Chapter two regarding the question of whether the increase in pharmaceutical patents has created a sufficient enough incentive to stimulate pharmaceutical innovation concludes, evidence does not indicate that a higher number of patents necessarily stimulates innovation even in countries with an established pharmaceutical base. Recent years have seen a gradual decline in the number of chemical entities in both LMICs and high income countries.

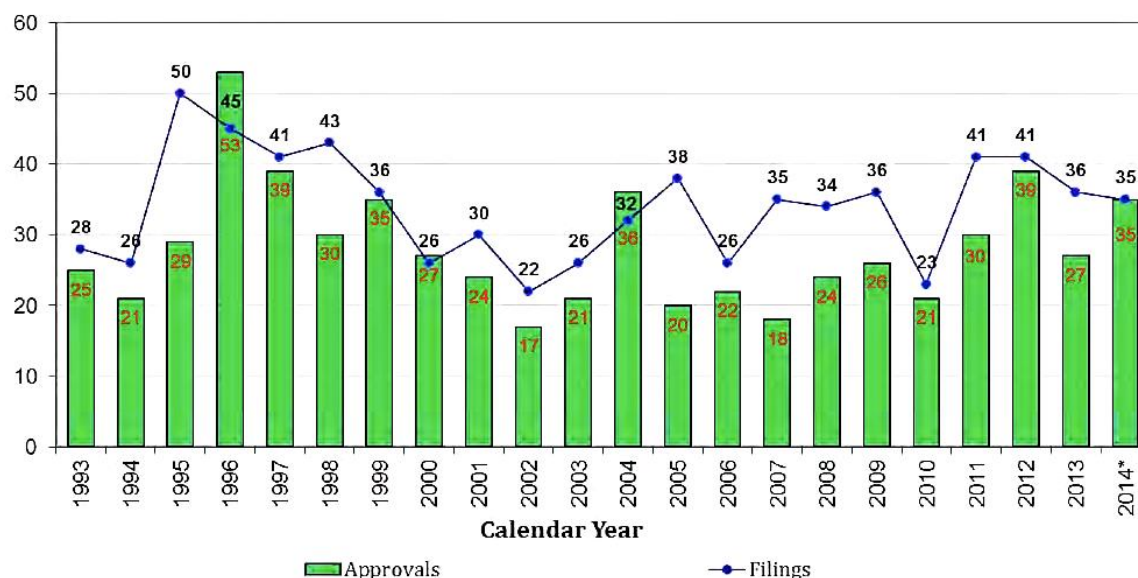
Figure 2: Drug Approvals up to 2013 by the US FDA

Source US FDA⁴³¹

⁴³⁰ See Correa (2007) ‘Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective’, WHO-ICTSD-UNCTAD working paper, [Online] Available:

<http://www.ictsd.org/themes/innovation-and-ip/research/guidelines-for-the-examination-of-pharmaceutical-patents>

⁴³¹ As presented in an article appearing on Forbes entitled ‘The Most Important New Drug of 2014’ [Online] Available: <http://www.forbes.com/sites/matthewherper/2014/12/30/the-most-important-new-drug-of-2014/>



According to a report by the US National Institute for Health (NIH), from 1989 to 2000, only 15 percent of all new drug approvals were for medicines that provide a significant clinical improvement.⁴³² At the same time, there has been a steady increase in the number of patents being granted over simple changes in chemistry or formulation of existing pharmaceuticals (e.g. polymorphs, combinations, dosage forms, isomers).⁴³³ If anything, experts argue that the granting of patents for incremental improvements to existing products stifles innovation rather than enabling it.⁴³⁴

For a country like Tanzania, with no originator pharmaceutical industry and a relatively small local industry that exclusively manufactures generic ARVs, there may be even less motive to prioritize pharmaceutical patent protection. Another factor that may be considered by policy makers in determining patentability criteria could be the number of local patent applicants in comparison to foreign applicants. The majority of patents being granted at the ARIPO Secretariat are to foreigners. For instance, in 2008, of 435 patent applications received by the ARIPO Secretariat, a

⁴³² National Institute for Health Care Management (NIH), (2002) *Changing Patterns of Pharmaceutical Innovation*, NIHCM Washington D.C. page 3. [Online] Available at: <http://www.nihcm.org/pdf/innovations.pdf>

⁴³³ Correa C, (2011), 'Pharmaceutical innovation, incremental patenting and compulsory licensing', South Centre, research Paper 41.

⁴³⁴ See Branstetter (2004).

mere 11 or approximately 2.5 percent were from residents of ARIPO Member States.⁴³⁵ Between 2009 and 2013, 2614 patents were filed and the vast majority came from applicants not residing in the ARIPO Member States. Similarly, the top nine patent applicants according to the WIPO patent database PATENTSCOPE, are multinational originator pharmaceutical companies. Consequently, in order to prevent patent barriers from impeding access to treatment in mainland Tanzania and Zanzibar, it follows that a policy that enables patents to be granted only where genuine contributions to the state of the art are made would be the most desirable. It also follows that the success of patent claims that relate to incremental innovation (formulations, salts, ethers and combinations for instance), second indications of pharmaceutical products and selection patents on a narrow gap of molecular compounds should be minimised.⁴³⁶

In countries in optimising the policy space afforded to them by the TRIPS Agreement have opted to define the concept of novelty in a variety of ways. The requirement of novelty usually means that the information relating to the patent application must not have been available to the public prior to the original application date (the priority date).⁴³⁷ In most European and developing country jurisdictions, this refers to information obtained by whatever means⁴³⁸ thereby placing a higher threshold on information being disclosed by the applicant to be genuinely new. The 2011 America Invents Act which simplified the pre-existing rules on novelty in the US,⁴³⁹ notes that a person shall be entitled to a patent unless:

“ (1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued [to another] . . . or in [another’s]

⁴³⁵ As per information obtained from WIPO’s statistical database in Marongiu, A (2011) ‘Non-Resident Patent Applications in the African Regional Intellectual Property Organization’ Mile 11 Thesis, World Trade Institute, Berne [Online] Available:

http://www.wti.org/fileadmin/user_upload/wti.org/1_masterprogramme/pdfs/Masters_thesis_Alessandro%20Marongiu.pdf

⁴³⁶ See Correa (2011) 22-23. Section 3(d) of India’s Patent Act of 2005 is regularly cited as an example of how a country can use patentability criteria effectively to meet public health concerns. See also Kapczynski (2009) and Basheer S, and Reddy P, (2008) ‘Ducking TRIPS in India: A Saga Involving Novartis and the Legality of Section 3(d)’, National Law School of India Review, volume 20, No. 2.

⁴³⁷ UNCTAD-ICTSD (2005) page 359.

⁴³⁸ Ibid UNCTAD-ICTSD (2005)359.

⁴³⁹ Merges R, (2012) ‘Priority and Novelty under the AIA’ Berkeley Law Technology Journal, Vol 27, 1023

application for patent [that is] published . . . [and that] was effectively filed before the effective filing date of the claimed invention.”⁴⁴⁰

Mainland Tanzania’s Patent Act, in defining what constitutes prior art⁴⁴¹ refers to the disclosure of information written or oral made anywhere in the world, which is a comparatively speaking high standard. The reference to a combination of disclosures oral, or written, made anywhere in the world would further raise the standard of novelty, in the public health interest of Mainland Tanzania. Zanzibar’s Industrial Property Act in defining novelty⁴⁴² explicitly refers to prior art which comprises of “*everything that can be derived from a combination of patents*. Because Zanzibar’s Industrial Property Act already excludes pharmaceutical products from patentability until 1 January 2016, or a later date agreed to by the Council for TRIPS, the implications of this provision on the patentability of pharmaceuticals, will not be immediately known.

The next opportunity for countries to further define patentability criteria is the requirement of inventive step, which defines the level of technical contribution required for a valid patent to be granted.⁴⁴³ The flexibility provided to WTO Members to define inventive step can be employed to reduce the likelihood of incremental inventions being patentable. In several European and developing country contexts the requirement is that of inventive step, whereas the US has a requirement of non-obviousness.⁴⁴⁴ As Barton noted, this lower standard of inventiveness applied in countries like the US has led to the granting of several patents, often with minor or trivial modification.⁴⁴⁵ A lower standard of inventiveness can also be used to artificially extend the duration of patent protection and to block generic competition. It may therefore be in the interests

⁴⁴⁰ See Section 102 of the Act which also contains a number of exceptions to this rule including disclosures made a year of less before the filing date and disclosures made in patent applications.

⁴⁴¹ According to Section 9(2):

“Everything made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) or by oral disclosure, use, exhibition or other non-written means shall be considered prior art provided that such making available occurred before the date of the filing of the application”

⁴⁴² Section 4(2)(a) reads:

“An invention shall be new if it is not anticipated by prior art, or where a theoretical person, who is highly skilled in the area, could not derive the invention from a combination of publications”

⁴⁴³ Correa (2007) at 4.

⁴⁴⁴ Which is why, footnote 5 of Article 27.1 of the TRIPS Agreement equates inventive step with non-obviousness, as noted in UNCTAD-ICTSD (2005) page 360.

⁴⁴⁵ Barton, J (2000) *Reforming the patent system*, Science Volume 287, 17, 1933-1934.

of countries with high burdens of disease such as Tanzania to facilitate competition by adopting a high level of inventive step.

The requirement of inventive step also determines what a person skilled in the art (such as a person trained and experienced in pharmaceutical formulation) could consider obvious in the light of such prior art. According to Correa, having a requirement for an inventive step:

*‘...implies that the “person skilled in the art” should be deemed to have some specialized knowledge and not simply somebody with very general or ordinary knowledge in the relevant technical field. A person skilled in the art is not just an expert in his technical field but a person who should have some degree of imagination and intuition. He should not only rely on the documents found in the novelty search, but apply his experience and his knowledge. Such an examiner should be particularly strict when examining the inventive step.’*⁴⁴⁶

Mainland Tanzania’s Patent Act in further defining an inventive step,⁴⁴⁷ notes that for the requirement of inventive step to be met, an invention “*would not have been obvious to a person skilled in the art on the date of the filing of the application.*” Zanzibar’s Act⁴⁴⁸ on the other hand considers a patent application as having passed the inventive step test if it would not have been obvious to a person “*highly skilled in the art*”. As discussed in chapter five, the implications of Zanzibar’s threshold of ‘highly skilled’ are that fewer patents are likely to be granted by a person with more expertise in the field of technology than a person who is ordinarily skilled.

Another important flexibility available to patent authorities in Zanzibar is an extremely broad provision in the Act which depending on how it is interpreted, provides for the exclusion of “*new uses or forms of known substances*” from patentability.⁴⁴⁹ This flexibility in essence, can be used to support a policy position that only genuinely innovative products, as opposed to those with incremental modifications are subject to patent protection, and is extremely broad in its wording without the types of qualifications that have been applied in a similar provision found in India’s

⁴⁴⁶ Ibid Correa (2007),

⁴⁴⁷ Section 10.

⁴⁴⁸ See Section 4(3).

⁴⁴⁹ Section 3(1)(v).

Patent Act of 2005. Section 3(d) of the Indian Patents Amendments Act prevents the patenting of new uses and new forms of known substances, but with the qualification that these new uses of forms do not enhance efficacy.⁴⁵⁰

Both mainland Tanzania and Zanzibar Acts provide protection for utility models even though the TRIPS Agreement does not explicitly require this.⁴⁵¹ The provisions on utility models are as a result of Tanzania's membership of ARIPO. The Harare Protocol provides for utility models as long as they meet criteria of novelty and industrial applicability.⁴⁵² Utility models have traditionally been used to offer a limited period of exclusivity for inventions that would not otherwise be protected by patents or other forms of intellectual property and can be a way of encouraging innovation among local inventors. Statistics from a number of countries in east Asia who made use of utility models suggest that, combined with a relatively weak intellectual property protection system which encourage the transfer of technology, utility models can encourage technological learning.⁴⁵³

While there is no internationally accepted definition of a utility model, it has been noted that they confer an exclusive right to the inventor that novelty is a criterion for protection and that utility models relate to the technical character of the invention, with the duration of protection varying between six and 25 years.⁴⁵⁴ Mainland Tanzania provides for 7 years of protection from the moment of filing⁴⁵⁵ without the possibility of renewal for 'Utility Certificates' as they are referred

⁴⁵⁰ Section 3(d) reads:

"the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in a new product or employs at least one new reactant." An explanatory clause notes that for the purposes of the Section, efficacy will be the key factor in determining whether incremental modifications involving *"salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance"* are patentable.

⁴⁵¹ Suthersanen notes that it may be arguable that Article 2(1) of the TRIPS Agreement recognises all relevant provisions of the Paris Convention provisions which recognises utility models. See Suthersanen U, (2006) *'Utility Models and Innovation in Developing Countries'*, UNCTAD-ICTSD Project on IPRs and Sustainable Development, Geneva [Online] Available: http://unctad.org/en/docs/iteipc20066_en.pdf

⁴⁵² See Section 3(2) of the Harare Protocol. Rule 18(2) of the Harare Protocol notes that the normal rules of novelty and inventive step agreed by the Contracting Parties of ARIPO shall apply to utility models.

⁴⁵³ Kumar N, (2002) *'Technology and Economic Development: Experiences of Asian Countries'* Commission of Intellectual Property Rights, Study Paper 1(b) London [Online] Available: http://www.iprcommission.org/papers/pdfs/study_papers/sp1b_kumar_study.pdf

⁴⁵⁴ Ibid Suthersanen at 2.

⁴⁵⁵ As per Section 74(5).

to under the Act, and requires that an invention be new and industrially applicable.⁴⁵⁶ There is no requirement for the applicant to demonstrate an inventive step, which, as discussed above is an important way to safeguard against the granting of protection for incremental innovations as opposed to genuine inventions. In the interests of increasing the likelihood of generic entry into the market, for stricter criteria should be implemented in Tanzania's legislation, especially for novelty, failing which could allow originator companies to obtain seven years of exclusivity for minor variations on existing inventions, thereby stifling competition. Zanzibar's Act confers 10 years of protection for utility models.⁴⁵⁷ On the matter of criteria for protection, Zanzibar's Act not only requires novelty, inventive step and industrial applicability, but has strict criteria for protection. Novelty is destroyed if it has been disclosed anywhere in the world, by written or oral disclosure, or use, prior to the filing date. The requirement of inventive step is not as stringent as in the Patent Act, requiring only that the invention does not result in a common manner "*from the prior art to a person having ordinary skill in the art*". This could be altered to refer to a person highly skilled in the art.

Other countries have explored innovative ways to safeguard against intellectual property being used as an unnecessary entry barrier to generic pharmaceutical competition. The Brazilian authorities enacted an intellectual property law⁴⁵⁸ to implement to the TRIPS Agreement with specific reference to Article 27.2 which provides grounds for the exclusion of certain subject matter from patentability. A few years later they introduced the concept of prior consent, which requires that even after pharmaceutical patent applications are reviewed and approved by the INPI, they should be sent to the Ministry of Health's surveillance agency (ANVISA) for 'prior consent' before a patent is granted. Even though the principle of prior consent has been both praised⁴⁵⁹ and criticised,⁴⁶⁰ Shadlen⁴⁶¹ notes that when it was initially introduced, the INPI, which, with the passing of a new law faced a flurry of pharmaceutical patent applications it may not have had the expertise to examine, may have welcomed ANVISA's role which resulted, according to sources

⁴⁵⁶ Section 74(1).

⁴⁵⁷ Section 24(1).

⁴⁵⁸ *Lei de Propriedade Industrial*, LPI, passed in 1996, which entered into force in 1997.

⁴⁵⁹ See Drahos P, (2010) "The Global Governance of Knowledge: Patent Offices and Their Clients" (Cambridge: Cambridge University Press, UK.

⁴⁶⁰ Kunisawa V, 'Patenting Pharmaceutical Inventions on Second Medical Uses in Brazil' (2009) 12 *Journal of World Intellectual Property* 297.

⁴⁶¹ Shadlen K, (2011) 'The rise and fall of "Prior consent" in Brazil', *The WIPO Journal*: Volume 3, Issue 1, 103.

in approximately 5 percent of pharmaceutical patents applications granted by INPI being rejected.⁴⁶² The active consultation by BRELA officials of the TFDA or experts in pharmacology before the ratification of ARIPO granted pharmaceutical patents may be a mechanism that countries like Tanzania with its two patent authorities may wish to investigate further as a way of reducing ever-greening.

d) Duration of Patent, Terms, Disclosure, Exhaustion of Rights and Exceptions to Patent Rights

The minimum duration of patent terms prescribed by Article 33 of the TRIPS Agreement, is a 20 year period that commences from the time a patent application is filed.⁴⁶³ Despite the LDC exemption being applicable to Tanzania, the patent legislation of both Mainland Tanzania and Zanzibar currently provide for patent protection on various subject matter. Zanzibar's Industrial Property Act provides for 20 years of patent protection⁴⁶⁴ while Mainland Tanzania provides for a 10 year patent term,⁴⁶⁵ both applicable from the date of filing. For Zanzibar, the patent term is not applicable for pharmaceutical products or processes given their exclusion from patentability as discussed above. As mainland Tanzania does not take advantage of the transition period and grants pharmaceutical patents, the 10 year patent term is a way to safeguard public health priorities, as there are no Tanzanian companies involved in pharmaceutical innovation. However, the 10 year patent term currently available in mainland Tanzania is in conflict with the 20 year period of patent protection granted by the Harare Protocol, another example of the policy misalignment that exists between the Harare Protocol and the enabling legislation of ARIPO Member States.

One of the key principles present in most modern patent laws is that of disclosure. As part of the social contract between an inventor and society, the inventor is required to disclose how the

⁴⁶² Shadlen K, (2009) 'The Politics of Patents and Drugs in Brazil and Mexico', Journal of Comparative politics, 42 (1). p 41-58 [Online] Available:

http://eprints.lse.ac.uk/27051/1/politics_of_patents_and_drugs_in_Brazil_and_Mexico_%28LSERO%29.pdf

⁴⁶³ Article 33 reads:

"the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." The meaning of Article 33 was confirmed in the WTO Dispute Settlement Panel report of *Canada- Term of Patent Protection*. See WT/DS170/R, paragraph 6.103.

⁴⁶⁴ Section 13(1)(a).

⁴⁶⁵ Section 39(1).

invention is carried out so that society may use the invention once a period of exclusive use of the invention granted to the inventor elapses.⁴⁶⁶ In addition to this requirement of disclosure, some countries, including the US place an additional requirement on the inventor to provide the best mode of invention.⁴⁶⁷ The disclosure requirement with an option to require the best mode of invention are reflected in the TRIPS Agreement in Article 29 of TRIPS which reads:

“1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.”

As an accommodation of the US law, Article 29 provides WTO Members with the option to require that the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date. This clause, meant to facilitate the transfer of technology from the inventor to society, presents an important opportunity for eastern and southern African countries interested in providing enabling legal environments to encourage local pharmaceutical industries. While mainland Tanzania's Patent Act requires disclosure of the best mode of carrying out the invention,⁴⁶⁸ Zanzibar's Industrial Property Act also in requiring disclosure of the best method known to the patent applicant at the time of application also requires that the disclosure of the invention shall be in a manner “sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art.”⁴⁶⁹ It could be argued that this places an additional

⁴⁶⁶ This was first articulated in the landmark case of *Liardet versus Johnson* [1778] 1 WPC 52 at 54 where Lord Mansfield stated that:

“the law relative to patents requires, as a price the individual should pay the people for his monopoly, that he should enroll, to the very best of his knowledge and judgment, the fullest and most sufficient description of all the particulars on which the effect depended, that he was at the time able to do.”

⁴⁶⁷ 35 U.S.C. No. 112, paragraph 1 (1984) provides that the patent specification should contain a written description of the invention, the manner and process of invention in full, clear and exact terms to enable any person skilled in the art pertaining to the invention to make and use the invention, and to provide the best mode known to the inventor.

⁴⁶⁸ Section 35(2)(a).

⁴⁶⁹ See Section 6(4) (a). Section 6(4)(d) describes a person having ordinary skill in the art as a citizen of Tanzania and who carries out his profession in Zanzibar, having acquired an average expertise and experience in the technical field of the claimed invention.

obligation on the inventor to disclose the invention in a way that local pharmaceutical manufacturers without highly specialized training, would be able to understand how to carry out the invention. The Act explicitly identifies technology transfer as a goal in authorizing the Registrar to adapt the description in foreign patent applications to the ordinary skill in the art of the citizens of Tanzania residing in Zanzibar.⁴⁷⁰

Another potential opportunity to reduce the cost of treatment for HIV, particularly where medicines are under patent in countries with significant generic pharmaceutical manufacturing capacity is parallel importation. For the purposes of being able to import patented medicines from the most affordable global source, the international exhaustion of rights doctrine would be most suitable for Tanzania. Zanzibar's Industrial Property Act provides for parallel importation with the adoption of an international exhaustion of rights doctrine.⁴⁷¹ This important flexibility is not available in the legislation of mainland Tanzania, which provides for national exhaustion of rights.⁴⁷² The issue is regulated in the Tanzania Food Drugs and Cosmetics Act⁴⁷³ which reads that:

“the Authority may if it is in the public interest so to do, authorise parallel importation of any drug.”

Limiting parallel importation only to instances where is considered to be in the public interest is unnecessary. The Patent law could be amended to explicitly provide for international exhaustion of rights.

e) Exceptions to Patent Rights, Compulsory Licensing and Government use

Another important opportunity available within the TRIPS Agreement to balance the rights of the patent holder with those of the consumer lies in Article 30.⁴⁷⁴ The wording of Article 30 provided

⁴⁷⁰ Section 6(4)(e).

⁴⁷¹ Section 12(4)(a)(i).

⁴⁷² Section 38(2).

⁴⁷³ See Section 73(2) of Act 1 of 2003.

⁴⁷⁴ Article 30 reads:

WTO Members with the policy space to determine circumstances under which exceptions will be provided to exclusive patent rights. Reasons to limit patent rights range from non-commercial use by the public sector to facilitating the generic entry of a competing product as soon as the patent term expires by applying for marketing authorisation before the expiry of the patent term.⁴⁷⁵ WTO Members are expected to comply with a three step test in applying Article 30 exceptions:

- (i) The extent to which the patent-holder's rights are curtailed should be limited;⁴⁷⁶
- (ii) The exception to patent rights should not unreasonably conflict with the normal exploitation of the patent;⁴⁷⁷ and
- (iii) The exception should not unreasonably prejudice the legitimate interests of the patent holder.⁴⁷⁸

For the purposes of increasing access to health technologies, the Article 30 exception of greatest significance is the bolar exception, as when correctly employed, it facilitates generic entry as soon as practicably possible, upon expiry of a patent. A 2010 study found that of 95 countries surveyed, 56 percent had incorporated the bolar exception into national legislation, although there is a large disparity (72 percent of OECD countries and 13 percent of African countries had incorporated the bolar exception into national legislation).⁴⁷⁹ Mainland Tanzania's Patent Act does not provide for a bolar exception, which may constitute an important omission, especially if industrial policy seeks to promote generic competition. Zanzibar's Industrial Property Act contains a clause on the bolar

"Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."

⁴⁷⁵ See UNCTAD-ICTSD (2005) at 430. This is referred to as the Bolar exception as discussed in the US case of *Roche Products v Bolar Pharmaceuticals*, 733 F.2d. 858 (Fed. Cir. 1984). The exception had been introduced into US law in 1984 to permit the testing of generic medicines to obtain bioequivalent certificates required to obtain marketing approval before the expiration of a patent.

⁴⁷⁶ UNCTAD-ICTSD (2005) at 434, referred to EC-Canada Panel report in concluding that it would be justified in reading the text literally, focusing on the extent to which legal rights have been curtailed, rather than the size or extent of the economic impact.

⁴⁷⁷ This is language that dates back to the Berne Copyright Convention, see Article 9(2).

⁴⁷⁸ According to the EC-Canada Panel Report at Paragraph 7:69

"To make sense of the term "legitimate interests" in this context, that term must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are "justifiable" in the sense that they are supported by relevant public policies or other social norms."

⁴⁷⁹ WIPO (2010), *Patent related flexibilities in the multilateral legal framework and their legislative implementation at the national and regional levels*, CDIP/5/4. Geneva [Online] Available: http://www.wipo.int/meetings/en/details.jsp?meeting_id=19686

exception.⁴⁸⁰ Mainland Tanzania's patent Act does not specify but implies that all forms of scientific research are included in its limitation of rights clause,⁴⁸¹ while Zanzibar's Industrial Property Act explicitly notes that the research exception applies to both scientific and commercial research.⁴⁸²

Mainland Tanzania's compulsory licensing provisions can be made more public health sensitive in a number of substantive and procedural ways. The Patent Act does not mention anticompetitive behaviour by the patent holder as a ground under which a compulsory license can be issued, despite the presence of flexibilities available under Article 31(k). Second, even though Article 31(b) removes the requirement for prior negotiations in the event of a national emergency or situation of extreme urgency, mainland Tanzania does not take advantage of this flexibility, opting only to waive the requirement for prior negotiations in the event of public non-commercial use.⁴⁸³ An amendment to the Act could increase this policy latitude. The final substantive point concerns the role of the courts. Mainland Tanzania's Act makes extensive reference to the role of the courts in the granting and administration of compulsory licenses. For instance, the courts must be satisfied that, there had been an attempt to negotiate a voluntary license,⁴⁸⁴ the courts have the right to award a compulsory license, to determine the terms and conditions associated with the license,⁴⁸⁵ the transfer⁴⁸⁶ and the cancellation⁴⁸⁷ of compulsory licenses.

The next point is one of procedure. The Act does not prescribe any guidance as to what constitutes a reasonable amount of time for negotiations for a voluntary license to be undertaken before an application for a compulsory license can successfully be brought.⁴⁸⁸ What constitutes a reasonable time for negotiations to be conducted may vary depending on the subject matter of the license,

⁴⁸⁰ Section 12(4)(a)(v).

⁴⁸¹ Section 38(1) notes that patent rights shall not apply for acts done for scientific research.

⁴⁸² Section 12(4)(a)(iii).

⁴⁸³ Under Section 62(2), public non-commercial use is the only ground for which the requirement of prior negotiations is waived.

⁴⁸⁴ Section 56.

⁴⁸⁵ Section 57.

⁴⁸⁶ Section 58.

⁴⁸⁷ Section 59.

⁴⁸⁸ Article 56(a) provides that a compulsory licensing application can only be successful if the applicant satisfies the court that:

"... he has asked the owner of the patent for a contractual licence but has been unable to obtain such a licence on reasonable terms and within a reasonable time."

with the reasonable time for voluntary negotiations involving essential medicines likely to be shorter than for instance, licenses for the manufacture of garden furniture. With this distinction in mind, any future amendments of the law could distinguish between what constitutes a reasonable period of time for the negotiation of voluntary licensing agreements involving essential and non-essential commodities, with the former being allotted a shorter period of time, and the classification of what is considered an essential commodity.

Zanzibar's recently drafted Patent Act has incorporated several of the flexibilities missing in Mainland Tanzania's Patent Act. For instance, anti-competitive behaviour such as the abuse of exclusive rights is a ground for which a compulsory license application may be brought.⁴⁸⁹ Also, the Act waives the payment of a royalty fee for compulsory licenses issued on the basis of anti-competitive behaviour,⁴⁹⁰ and removes the need for prior negotiations with the patent holder.⁴⁹¹ The Act also specifies what constitutes a reasonable amount of time thus further defining Article 31(b) of the TRIPS Agreement. On one hand, if a request to negotiate a voluntary license has not resulted in the agreement of a licensing agreement on reasonable terms and conditions within 90 days, a compulsory license may be issued.⁴⁹² However a second provision authorizes a request to be made to the relevant authority to issue a compulsory license within 45 days from the request for a contractual license, if the parties are unable to reach agreement on reasonable terms and conditions.⁴⁹³ Finally, Zanzibar's compulsory licensing provisions are far less likely to be delayed by legal disputes. The primary authority entitled to issue a compulsory license is the minister responsible for industrial property matters, with occasional guidance (in the limited circumstances around determining what constitutes anti-competitive behaviour) from administrative or judicial bodies.⁴⁹⁴

Consideration must also be given to the 30 August 2003 Agreement and the 2005 Decision to Amend Article 31 of TRIPS, as discussed in chapter two. Although this decision awaits the ratification by at least two-thirds of WTO Members to come into effect and questions continue to

⁴⁸⁹ Section 14(1)(a) (ii) and (iii).

⁴⁹⁰ Section 14(1)(b).

⁴⁹¹ Section 14(6)(b).

⁴⁹² Section 14(1)(a)(vi).

⁴⁹³ 14(6)(a). It is unclear whether the 90 day or 45 day period is applicable.

⁴⁹⁴ Section 14(1)(a)(ii).

be raised by several WTO Members as to the effectiveness of the mechanism to resolve the problem posed to countries without sufficient pharmaceutical manufacturing capacity, the 2003 Agreement entitles countries to use the temporary waiver, without necessarily ratifying the amendment to Article 31. The waiver can be incorporated into national legislation to facilitate its use. United Republic of Tanzania has not ratified Article 31*bis* amendment and Mainland Tanzania's legislation pre-dates the 30 August 2003 Agreement and is thus not reflected into the Patent Act. Zanzibar on the other hand has chosen to incorporate the Decision into its Patent Act.⁴⁹⁵ Although Zanzibar has no domestic manufacturing capacity, this provision allows the authorities to re-export any quantity of medicines received under the 30 August 2003 Mechanism, under, hypothetically for instance, a pooled procurement agreement that the EAC Partners or SADC Member States may have used to purchase essential medicines, which is a potentially important pathway to the sustainability of treatment programmes in the country.

f) Provisions relating to Intellectual Property Enforcement

Part III of the TRIPS Agreement regulates the minimum standards on intellectual property enforcement, required of WTO Members. These relate to remedies and procedures of both an administrative and judicial nature. A general principle that is applicable to part III of the TRIPS Agreement is the requirement that all rules and procedures be fair and equitable.⁴⁹⁶ This principle is applicable not just to right holders but all stakeholders including generic companies, government authorities and consumers. Additional principles may be of interest to Mainland Tanzania and Zanzibar. First, intellectual property enforcement procedures should not constitute a legitimate barrier to trade;⁴⁹⁷ Second, decisions on the merits of a case shall be made expeditiously, and only on the basis of evidence which the parties were offered an opportunity to be heard.⁴⁹⁸ Third, any

⁴⁹⁵ Section 14(1)(b) of the Act waives any remuneration due to a patent holder if a compulsory license under the 30 August 2003 Agreement results in the importation of a product into Zanzibar. Section 14(7) complies with the requirement of Article 31(f) that a compulsory license shall be predominately for domestic use, but then explicitly lists any exports that take place under the 30 August 2003 Agreement, as being exempt from the requirement of predominantly domestic use.

⁴⁹⁶ According to Article 41.2 of TRIPS, the procedures should not be unnecessarily complicated, costly, or entail unreasonable time-limits or unwarranted time delays.

⁴⁹⁷ See Article 41.1.

⁴⁹⁸ See Article 41.3.

decisions made by administrative or judicial authorities on intellectual property enforcement should be subject to review.⁴⁹⁹

An essential component of the TRIPS Agreement in the context of countries being able to rely on generic medicines to sustain national treatment programmes is the definition of “counterfeit,” which refers to a specific form of trademark infringement. Article 51 of the TRIPS Agreement,⁵⁰⁰ defines trademark counterfeiting as referring to:

“Any goods, including packaging, bearing without authorization a trademark which is identical to a trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.”

The second key provision of the TRIPS Agreement in relation to access to health technologies is Article 61, which requires criminal sanctions in the event of:

“wilful trademark counterfeiting or copyright piracy on a commercial scale”

Another relevant section of the TRIPS Agreement under the enforcement chapter relates to the rules of evidence which enable a judicial authority to order both parties to provide evidence to substantiate their assertions when a proceeding on intellectual property enforcement is taking place,⁵⁰¹ and to make preliminary or final determinations on the basis of what evidence is provided, in the event a party to the proceeding refuses or fails to provide evidence within a reasonable period of time.⁵⁰²

⁴⁹⁹ Article 41.4 reads:

“Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member’s law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case.”

⁵⁰⁰ Footnote 14(a), in particular.

⁵⁰¹ See Article 43.1 of TRIPS.

⁵⁰² See Article 43.2 of TRIPS.

In general, the Patents Amendment Act applicable in Mainland Tanzania does not refer to most of the provisions in chapter III of the TRIPS Agreement, which it need not, given its LDC status. However, Section 70 of Patents Registration Act of Mainland criminalises patent infringements, even introducing the possibility of a lengthy custodial sentence which is certainly not required by the TRIPS Agreement.⁵⁰³ The criminalization of intellectual property infringement for anything other than for the wilful trademark infringement and copyright piracy on a commercial scale could be have unintended and negative consequences. The South African Judge Harms, has noted several reasons why the criminalisation of intellectual property infringements could be problematic. Some of these include the reminder that a large number of patents are revoked during litigation and that patent invalidity is often a defence to allegations of infringement, that patents can sometimes cover more than one invention, that most criminal courts are not qualified to handle patent litigation and that it can be almost impossible for customs and law enforcement officials to determine whether a product the right holder alleges is infringing on a patent, is actually doing so.⁵⁰⁴ Criminalising patent infringements in such a broad manner could result in the use of limited state resources to enforce what are private rights. Considering that the majority of patent applications at the ARIPO Secretariat pertain to pharmaceutical products, it is not difficult to foresee examples where this might occur.

Another key shortcoming of the existing legislation in Mainland Tanzania lies outside of the scope of the Patent Act. In 2008, regulations to supplement the Merchandise Marks Act of 1963⁵⁰⁵ were enacted⁵⁰⁶ and contain a definition of counterfeit,⁵⁰⁷ which, if broadly interpreted could exceed the narrow reference to trademarks contained in the TRIPS Agreement and include generic medicines. Given the conflation between counterfeit and generic medicines within the EAC in

⁵⁰³ According to Article 70.1 of the Patents Registration Act:

“Any person who intentionally infringes a patent shall be guilty of an offence and shall, on conviction be liable to a fine not exceeding five hundred thousand shillings or to a term of imprisonment of five years or to both that fine and imprisonment and forfeiture of the goods made through that patent.”

⁵⁰⁴ Harms L, (2007) The Enforcement of Intellectual Property Rights by Means of Criminal Sanctions: An Assessment, WIPO/ACE/4/3, page 15, [Online] Available:

http://www.wipo.int/edocs/mdocs/enforcement/en/wipo_ace_4/wipo_ace_4_3.pdf

⁵⁰⁵ Cap 85 of 1963.

⁵⁰⁶ As per Government Notice 89 enacting the Merchandise Marks Regulations

⁵⁰⁷ For instance, Section 2 of the Merchandise Marks Regulations defines a counterfeit as:

“the manufacturing, producing, packaging, re-packaging, labeling or making whether in Tanzania or elsewhere, of any goods, where those protected goods are imitated in such a manner and to such a degree, that those other goods are identical or substantially similar copies of the protected goods.”

recent years as discussed in chapter two and the detention of legitimate generic medicines predominantly manufactured in India, and detained in various European transit hubs en route to a number of African and Latin American countries, any definition of the term counterfeit that could be broadly interpreted to negatively impact on generic medicines could be problematic and should be narrowed accordingly.

(g) Test data protection

As noted above in chapter two, Article 39.1 and 39.2 of the TRIPS Agreement require WTO Members to the protection undisclosed information⁵⁰⁸ against unfair commercial use and entitles natural and legal persons to prevent the disclosure, acquisition or use of information in a manner contrary to honest commercial practice where the information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

Article 39.3 requires the protection of undisclosed test or related data required for the marketing approval of pharmaceutical products, the generation of which involved a considerable effort, from unfair competition.⁵⁰⁹ Many authors argue that this requirement to protect undisclosed test data refers only to originator data for new chemical entities and that Article 39.3 does not apply where for instance, marketing approval is granted by the TFDA or ZFDB, relying on the existence of a prior registration elsewhere.⁵¹⁰ As noted in chapter two, there is no precedent on the interpretation

⁵⁰⁸ Regarded as a form of intellectual property under Article 1.2 of TRIPS.

⁵⁰⁹ An important clarification to Article 39 is provided in footnote 10 found in the TRIPS Agreement:

“For the purpose of this provision, “a manner contrary to honest commercial practices” shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.”

⁵¹⁰ See UNCTAD-ICTSD (2005) at 530.

of Article 39 of TRIPS beyond the dispute between the US and Argentina on the interpretation of Article 39.⁵¹¹ For LMICs, particularly those with high burdens of disease, an interpretation which prevents the drug regulatory authority from making use of information available to it, including information in the files of competitors such as an originator company to determine the safety, quality and efficacy of generic medicines would be time consuming and wasteful. Also, given the high level of reliance of Tanzania on generic medicines, an interpretation that favours the earliest entry of generic products with a corresponding increase in competition could be the priority of the authorities in mainland Tanzania and Zanzibar.⁵¹²

Yet, Zanzibar's Industrial Property Act ⁵¹³appears to require a minimum period of 5 years during which time generic pharmaceutical companies would be precluded from relying on test data submitted by an originator company to the TFDB. This may produce a period of exclusivity where, despite the availability of several public health related TRIPS flexibilities in the Patent Act, a period of test data exclusivity may prevent generic competition.⁵¹⁴ The period of test data exclusivity is somewhat moderated with the inclusion of a sub-section⁵¹⁵ which prescribes that, upon agreement of “*adequate compensation*” by the originator and generic company, or where there is a failure to agree, then upon the payment of an amount set by the ZFDB, the originator's test data may be relied upon by a generic company on a limited number of grounds⁵¹⁶ These include circumstances where the obtaining of the test data resulted in the “*suffering of humans and animals*”, in situations of extreme urgency, failure to commercialize the originator product within a reasonable period of time after the obtaining of marketing approval or where the data concerns a product for which a compulsory license has been issued, subject to the payment of a payment of adequate remuneration that also takes into account the commercial value of the test data. The Act

⁵¹¹ Argentina- Patent Protection for Pharmaceuticals and Test Protection for Agricultural chemicals (WT/DS171/1)

⁵¹² See Correa C, (2002) ‘Protection of Data Submitted for the Registration of Pharmaceuticals. Implementing the Standards of the TRIPS Agreement’, South Centre, Geneva

⁵¹³ Section 72(5) (a) and (b).

⁵¹⁴ Section 78 of the Act also provides for a range of remedies in the event a court rules that unfair use of test data occurred in terms of Section 72 of the Act, which includes the authority to order the court to cancel the marketing approval of the infringer, payment of damages by the government authority to the originator company for unauthorized disclosure of test data, or the payment of adequate compensation to the originator.

⁵¹⁵ Section 72(5)(c).

⁵¹⁶ Section 72(5)(c)(i),(ii)(iii) and (iv).

also notes that pharmaceutical test data shall only be protected after the expiration of the LDC waiver.⁵¹⁷

While these attempts to mitigate data exclusivity may be useful safeguards, the larger question to be asked is why authorities in Zanzibar opted to provide for five years of test data exclusivity, considering that the origins of a five year data exclusivity proposal are from the business communities of developed countries.⁵¹⁸ The fact that data exclusivity has been agreed to by several LMICs through intellectual property chapters contained in Free Trade Agreements involving developed countries,⁵¹⁹ and the mounting evidence as discussed in chapter two which shows that data exclusivity may impede generic competition ⁵²⁰ support the argument that Zanzibar should not be providing for data exclusivity in its Industrial Property Act.

4.4 Conclusion

Despite the discussion of the TRIPS flexibilities available to Mainland Tanzania and Zanzibar and the appraisal of the extent to which they have been incorporated into enabling legislation and regulations, it is important to remember that neither Mainland Tanzania or Zanzibar are currently required to provide any level of intellectual property protection because of the LDC waiver. Although the likelihood of further waivers being available to LDCs like the United Republic of Tanzania exists, both territories already have long standing legislation on various aspects of intellectual property that impacts on access to treatment. A blanket rejection of intellectual property legislation because a country is entitled to do so, is not necessarily in the developmental interest of even an LDC like Tanzania. There may be some aspects of intellectual property regulation that may be within its advantage to adopt, such as a regime on access and benefit sharing and the regulation of bio-prospecting.

⁵¹⁷ Section 72(5)(h).

⁵¹⁸ As per the “*Statement of views of the European, Japanese and the United States Business Communities*” noted in UNCTAD-ICTSD (2005) at 523.

⁵¹⁹ See for instance, Article 15 of the Free Trade Agreement between the US and the CAFTA countries, Article 15.10 of the US Morocco FTA and Article 4 of the EU-Lebanon Association Agreement.

⁵²⁰ As noted above, a 2007 draft of the Industrial Property Bill of Zanzibar on file with the author, prepared by WIPO contained a lengthy data exclusivity clause.

The first hypothesis advanced in chapter one is supported by fact that Tanzanian authorities to date, are heavily reliant on donor support to sustain national HIV treatment programmes. This may account for the lack of urgency in comprehensive legislative reforms. While Zanzibar passed patent legislation in 2008, mainland Tanzania is yet to do so, and as demonstrated above, the country is still heavily reliant on foreign donor assistance to fund its national treatment programmes for HIV, TB and malaria. Another factor has been the role of various bilateral and multilateral providers of technical support in giving what is unlikely to be consistent advice to national institutions responsible for the administration of intellectual property. As noted by a government official, mainland Tanzania's failure to pass draft legislation on industrial property can also be attributed to the decision to first finalise an IP strategy with assistance from WIPO, which it is believed, would better inform legislation in the country's best interests.

The fact that a comparatively low number of staff employed both at BRELA and COSTECH have the significant expertise on intellectual property issues highlights the capacity constraints facing Tanzania, a fact under-scored by the provision of technical assistance by a plethora of institutions which may not necessarily align with the country's objectives around the maintenance of sustainable national treatment programmes.

The third hypothesis advanced in chapter one, namely that a significant degree of policy incoherence in the form of national level legislation and regional initiatives, which if not addressed by law reform and increased co-ordination could undermine the incorporation and use of TRIPS flexibilities in the national and regional level, thus bringing the sustainability of treatment programmes into question is validated by the country example of Tanzania in a number of ways. First, although it is one country, intellectual property matters continue to be dealt with separately between the territories of mainland Tanzania and Zanzibar, each with their separate pieces of legislation each containing different degrees of public health related TRIPS flexibilities. This has the potential to generate complications when attempts are made to use public health related flexibilities. In this regard, Zanzibar's Act, because it was only enacted more recently, contains significantly more public health sensitive provisions such as the LDC exemption on pharmaceutical patents, provisions on pre-grant patent oppositions, provisions to facilitate the use of the 30 August 2003 Mechanism, the exclusion of various subject matter from patentability, the

inclusion of principle of the international exhaustion of rights, the inclusion of important Article 30 exceptions, and relatively streamlined and user friendly compulsory licensing provisions.

For a territory of a little more than a million people and no local pharmaceutical manufacturing industry like Zanzibar, a regulatory environment that supports the importation of pharmaceutical products, as well as the regional co-operation in their procurement and re-exportation is essential. The opportunity exists to further improve the legislative framework in Zanzibar by removing all references to test data exclusivity, which if left in its current state, could constitute a key impediment to treatment access particularly as multilateral funding for national treatment programmes declines. Mainland Tanzania by virtue of its older Patent Act has far fewer public health related flexibilities. Mainland Tanzania's patent legislation requires significantly more reform to fully incorporate flexibilities and to remove provisions around intellectual property enforcement that exceed the minimum requirements of the TRIPS Agreement. With a small but growing local pharmaceutical industry and as a country heavily reliant on generic medicines, the existence of legislation that may limit the availability of generic competition could have serious implications on the long term sustainability of treatment programmes. Ultimately, the political question regarding the utility and practicability of operating two patent systems in an LDC, should be addressed if policy coherence is to be addressed.

The other aspect of policy incoherence relates to the compatibility of mainland Tanzania and Zanzibar's legislation with the Harare Protocol of ARIPO. At present, Tanzania's membership of ARIPO, and the latter's implementation of certain provisions of TRIPS such as Article 27, arguably places even more intellectual property obligations on it than the TRIPS Agreement may require of developing countries. It should also be remembered that even if the laws of Zanzibar and mainland Tanzania are reformed to incorporate more public health related TRIPS flexibilities than they currently contain, the fact that pharmaceutical patents are examined and granted by the ARIPO Secretariat may continue to result in the granting of patents that are not be in the public health interests of the country. Two solutions present themselves to this dilemma: first, there should be greater substantive scrutiny of patents that are granted by the ARIPO Secretariat by BRELA and the Zanzibar Registry of Patents to determine whether it is in the national interest that patents be granted in Tanzania. Second, there may be a need to reform the rules and procedures of

the Harare Protocol to better represent the strategic objectives of its members. This will be discussed in more detail in Chapter six.

It should be noted that flexibilities which appear in Zanzibar's law regulatory environment but are absent in mainland Tanzania's include remedies in intellectual property legislation for anti-competitive conduct. An opportunity exists to increase the remedies available to authorities for anti-competitive behaviour in Zanzibar's Act and to draw a clearer nexus between competition law and access to treatment under both competition and intellectual property law in Mainland Tanzania.⁵²¹ Finally, a greater degree of policy coherence is needed to balance the policy objectives of the country which include a desire to promote a local pharmaceutical industry and domestic innovators while keeping the costs of national ART programmes sustainable. This requires greater co-ordination between the various institutions with a vested interest in intellectual property policy in both mainland Tanzania and Zanzibar which, despite its more public health sensitive legislative framework, has no ARV pharmaceutical manufacturing industry and is thus reliant on mainland Tanzania and foreign pharmaceutical manufacturers as a source of health technologies.

⁵²¹ See the Fair Competition Act of 2003.

5 The Incorporation of Public Health Related TRIPS Flexibilities into Patent, Competition and Health Legislation in South Africa: Impact on Access to Health Technologies

“South Africa is now ground zero for debate on the value of strong IP protection. If the battle is lost here, the effects will clearly resonate... without a vigorous campaign, opponents of strong IP will prevail – not just on South Africa but in much of the developing world.”

Excerpt from a leaked 2013 proposal by lobbying firm Public Engagement Affairs to Pharma

5.1 An Introduction to Legislation with Implications on Treatment Access

The Republic of South Africa maintains a complex network of laws and policies that can be employed to facilitate access to health technologies. While comprehensive in scope, the combination of laws and regulations giving effect to public health related TRIPS flexibilities are both outdated and contain significant gaps, some of which may prove to impede treatment access to health technologies. As will be discussed later in the chapter, South Africa is one of a small number of countries in eastern and southern Africa financing the majority of its AIDS response, a noteworthy feat given that the country is home to the largest number of people living with HIV globally.

As postulated by the first hypothesis in chapter one, the vast majority of people on ART are still on first line treatment, which remains significantly more affordable than second and third line treatment regimens. Public health related TRIPS flexibilities will become more central to sustaining treatment programmes as patients move to newer versions of ART, some of which may see greatly reduced competition from generic manufacturers for prolonged periods of time.

The second hypothesis advanced in chapter one asserts that there are capacity constraints within the relevant government departments in eastern and southern Africa that hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and the use of these flexibilities when needed. While the South African government retains a comparatively large

degree of capacity within its government departments, this chapter will demonstrate that legislative gaps and capacity constraints particularly around the criteria for patentability could undermine government's plans to facilitate the development of a generic pharmaceutical industry and sustain national treatment programmes. Finally, the third hypothesis advanced in chapter one namely, that a significant degree of policy incoherence exists in the form of national level legislation and regional initiatives, which if not addressed by law reform and increased co-ordination, could undermine the incorporation and use of TRIPS flexibilities in the national and regional level, will also be tested in this chapter.

5.1.1 South Africa's Constitution, Bill of Rights and the Right to Health

Chief among the available legal instruments in South Africa is the Constitution,⁵²² adopted following the end of apartheid. The South African Constitution is widely lauded for its objectives to create a more equitable and inclusive society and contains a Bill of Rights⁵²³ of which the right to health, Section 27(1), is a key component. It provides that:

"everyone has the right to have access to health care services including reproductive health care."

The South African Government is required according to Section 27(2), to:

"take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights."

In addition, Section 27(3) states that no one can be denied emergency medical treatment.⁵²⁴ Reasonableness has proven to be an important component of the Constitutional Court's decisions

⁵²² The Constitution of the Republic of South Africa, 1996, was approved by the Constitutional Court (CC) on 4 December 1996 and came into effect on 4 February 1997.

⁵²³ The Constitutional Court has handed down a number of progressive judgments on civil, political, and socio-economic rights present in the Bill of Rights ranging from the abolition of the death penalty (*The State v Makwanyane and Another*, 1995, ZACC3 at 151, 1995 (3) S.A. 391) to the affirmation of the right to adequate housing (*Government of South Africa v Grootboom and others* 2001 (1) SA 46 (CC), 2000 (11) BCLR 1169 (CC) and equality for same sex couples to enjoy the same benefits and entitlements as married people with the case of *The Lesbian and Gay Equality Project and Eighteen Others v Minister of Home Affairs* 2006 (1) SA 524 (CC) (1 December 2005).

⁵²⁴ This was interpreted by the Constitutional Court in the case of *Soobramoney v Minister of Health [Kwazulu-Natal]* 1998 (1) SA 765 (CC), to be a right insofar as the State fairly balanced available resources with those requiring

in interpreting the duty of the state to fulfil the rights enshrined in the Bill of Rights. The landmark decision of the Constitutional Court on treatment access matters remains the 2002 case of *The Minister of Health and Others v the Treatment Action Campaign and Others*.⁵²⁵ The ruling came at a time when the government despite having the largest population of people living with HIV in the world, and the resources to provide nevirapine to HIV positive pregnant women to reduce the risk of HIV transmission to their new-borns, failed to do so, citing the costs of treatment and the toxicity of ARVs including zidovudine and nevirapine.⁵²⁶ In ordering the government to provide nevirapine to roll out a prevention of mother to child transmission (PMTCT) programme “without delay”, the Constitutional Court also required the government to take reasonable measures to expand testing facilities to facilitate the use of nevirapine.

5.1.2 A brief overview of the South African Regulatory framework

In addition to the Constitution there are a number of domestic laws that can be said to give effect to public health related flexibilities available in the TRIPS Agreement. These include provisions contained in the Patent Act,⁵²⁷ Counterfeit Goods Act⁵²⁸ Intellectual Property Rights From Publicly Funded Research and Development Act⁵²⁹ and Medicines and Related Substances Control Act,⁵³⁰ most of which are administered by different institutions who may have different priorities and objectives which may not necessarily be aligned with each other. The emergence of a draft intellectual property Policy⁵³¹ in September 2013, developed after years of consultations is an important step towards the harmonization and alignment of the various pieces of applicable legislation. Treatment activists and patients await the finalization of the draft policy⁵³² released

indefinite medical treatment which, in the case of kidney dialysis, was too expensive to be made available to everyone who needed it.

⁵²⁵ 2002 (10) BCLR 1033 (5 July 2002).

⁵²⁶ The circumstances leading up to the filing of the suit by the TAC and others in the High Court, the process of appeal by the government and the eventual ruling are comprehensively described in Kapczynski A, and Berger J, ‘The Story of the TAC Case: The Potential and Limits of Socio-Economic Rights Litigation in South Africa’ in Hurwitz D, and Satterwaite M, eds. “Human Rights Advocacy Stories (2009) Volume 47 Foundation Press.

⁵²⁷ Act 57 of 1978.

⁵²⁸ Act 37 of 1997.

⁵²⁹ Act 51 of 2008.

⁵³⁰ Act 101 of 1965.

⁵³¹ See Government Notice 918 of 2013 issued by the Minister of Trade and Industry Rob Davies released the draft policy and invited members of the public to make comments.

⁵³² Treatment activists led by the TAC, MSF and Section 27 have been pressing the government to finalize the draft policy as a matter of urgency through a campaign known as “fix the patent laws”. In October 2013, more than 130

after the amendments of various pieces of intellectual property related legislation in recent years. These include the Intellectual Property from Publicly Funded Research and Development Act as well as the Intellectual Property Laws Amendment Bill,⁵³³ meant to provide protection for traditional knowledge into several pieces of legislation,⁵³⁴ both of which were the subject of much criticism.⁵³⁵

Intellectual property legislation aside, South Africa's Competition Act⁵³⁶ also contains provisions which give effect to public health related flexibilities in the TRIPS Agreement. As discussed above in Chapter three, the Act has been successfully employed by treatment activists to reduce prices of certain ARVs on a number of occasions. There are also a range of laws and regulations overseeing the registration, distribution and dispensing of health technologies regulated by the Medicines and Related substances Control Act. The implications of these laws and regulations insofar as they are relevant to the TRIPS Agreement will also be discussed in more detail below.

5.2 The Public Health Situation in South Africa and Access to Health Technologies

With an estimated population of almost 52 million at the end of 2011⁵³⁷ or less than 1 percent of the global population, South Africa remains the country with the highest number of people living with HIV in the world, with an estimated incidence of 6.1 million cases or more than 17 percent of the estimated global AIDS population at the end of 2012.⁵³⁸ With more than 500 000 incidents of TB at the end of 2011, South Africa is also home to the third largest population of people living with TB after India and China. This comes as little surprise when considering that people living

organizations wrote a letter to the Minister of Trade urging swift adoption of the Draft IP Policy, followed by a second open letter in June 2014 signed by more than 70 organisations.

⁵³³ Of 2011.

⁵³⁴ Including the current Trade Marks, Copyright, Designs and Performance Protection Acts.

⁵³⁵ See for instance an opinion piece by Owen Dean in IP Watch entitled *From South Africa Keeping Traditional Knowledge Traditional* [Online] available: <http://www.ip-watch.org/2012/12/07/from-south-africa-keeping-traditional-knowledge-traditional-2/>. See also Barrett, A (2010) 'Lessons from Bayh-Dole: Reflections on the Intellectual Property Rights from Publicly Financed Research and Development Act (South Africa)', *Journal for Juridical Science*, Vol. 35, 30-69.

⁵³⁶ Act 89 of 1998.

⁵³⁷ More information on the South African census results are [Online] Available: <http://www.southafrica.info/about/people/population.htm#.U7CJTqHD-P8>

⁵³⁸ UNAIDS (2013) *Report on the Global AIDS Epidemic* [Online] Available: http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2013/gr2013/unaids_global_report_2013_en.pdf

with HIV are 20 to 37 times at greater risk of contracting TB. MDR-TB and XDR-TB continue to pose grave challenges with approximately one out of every six global XDR-TB cases having been reported in South Africa.⁵³⁹

National HIV treatment programmes for HIV have been scaled up rapidly since the intransigence associated with the Mbeki Administration's AIDS response. In 2002, there was still no national HIV treatment programme. A little more than a decade later, the country had the largest treatment program in the world, thanks to a massive investment in the AIDS response by the South African government. According to UNAIDS, South Africa has made the highest domestic investment in AIDS among all LMICs, having invested US\$ 1.9 billion in 2012, a 500 percent increase between its investment between 2006 and 2011.⁵⁴⁰ As a consequence, as of October 2012, approximately 2 million people were on ART through the national health care system.⁵⁴¹

As noted above, the level of domestic investment by the South African government in its AIDS response has borne fruit because the vast majority of patients on ART in South Africa are still on first line ART regimens, which are affordable. However, public health related TRIPS flexibilities will begin to play a greater role as multilateral funding declines. According to an intervention by the Director-General of the Department of Health at the January 2014 WHO Executive Board, only 4 percent of people on ART through the government sponsored treatment programme were on second line treatment. This number must be increased to 14 percent. The Director General went on to emphasise the importance the public health related TRIPS flexibilities in facilitating access to new-generation ARVs increasingly being patented in countries with significant pharmaceutical manufacturing capacity.⁵⁴²

South Africa has been lauded not only for the rapid expansion of its state run ART program,⁵⁴³ but also for its ability to effectively reduce treatment costs. In December 2010, the Department of

⁵³⁹Stop TB Partnership (2012), 'Tuberculosis and mining: A challenge to a key Southern African economic sector', WHO, Geneva.

⁵⁴⁰ See UNAIDS World AIDS Day Report at 21.

⁵⁴¹ See Irin news story of 9th October 2012 'Revamped AIDS Council Makes its debut' [Online] Available: <http://www.irinnews.org/Report/96492/SOUTH-AFRICA-Revamped-AIDS-council-makes-its-debut>

⁵⁴² The intervention by Director General Matsoso is [Online] Available: <http://keionline.org/node/1913>

⁵⁴³ UNAIDS (2012) 'Report on the Global AIDS Epidemic' Geneva [Online] Available:

Health announced a new government tender which introduced a reference price for various medicines based on information obtained from various databases including the Clinton Health Access Initiative and the WHO GPRM. The reference prices were considered by the government as an indication of what prices the government expected pay for the various medicines on tender. In addition to mechanisms developed to promote price stability for the duration of the contract period, the government developed a mechanism to systematically determine contract winners and volume allocations. These and other measures resulted in reduce expenditure of ARVs by 53 percent, amounting to cost savings of US\$ 685 million over the 2011-2012 period.⁵⁴⁴ The same approach was used in 2011 for a government tender for TB for which it was estimated that best practice interventions to prevent and treat TB would cut treatment and related costs by approximately US\$ 316 million.⁵⁴⁵ However, the success in treatment scale up and cost reduction are tempered by the fact that with the revision of the criteria for treatment eligibility by the WHO in 2013, a staggering 5.1 million people were eligible for ART in South Africa as of the end 2013.⁵⁴⁶

While impressive gains have been made in treating the AIDS and TB epidemics in South Africa over the past decade, the disparity in cost between the most affordable first generation ARVs and the newer generation, of more effective and less toxic first generation ARVs as well as second and third generation ARVs remains high in many instances. MSF estimates that of the approximately 15 000 patients on ART in Khayelitsha township in the Cape Town area, 12 percent had to be moved onto 2nd generation treatment within five years because of drug-resistance.⁵⁴⁷ It is estimated that the cost of the most commonly used second generation ART combination the public sector (a combination of zidovudine, lamivudine and lopinavir/ritonavir) cost approximately US\$ 535 per patient per year. According to the WHO, third line treatment comprising of raltegravir, etravirine and darunavir/ritonavir cost approximately US\$ 2 335 per patient per year in 2014.⁵⁴⁸

http://www.unaids.org/en/media/unaids/contentassets/documents/epidemiology/2012/gr2012/20121120_UNAIDS_Global_Report_2012_en.pdf

⁵⁴⁴ see also UNAIDS (2013) 'Efficient and sustainable AIDS responses: Case Studies on Country Progress' [Online] Available:

http://www.unaids.org/sites/default/files/media_asset/JC2450_case-studies-country-progress_en_0.pdf

⁵⁴⁵ Stop TB Partnership (2012).

⁵⁴⁶ Ibid UNAIDS 2013.

⁵⁴⁷ As per opening remarks by Vuyiseka Dubula, then Chairperson of TAC and Mark Heywood, the Executive Director of Section 27, made in November 2012 at a global activist meeting on the MPP and voluntary licenses.

⁵⁴⁸ According to the WHO GPRM.

In addition, the cost of TB treatment is extremely high thanks in part to a patent on an important medicine linezolid used to treat MDR TB. In early 2014, linezolid cost as much as US\$ 65 per pill which amounted to as much as US\$ 49 000 per patient in the private sector for a course of treatment. Pfizer sold linezolid to the South African Government at a discount price of US\$ 27 per pill despite the availability of generic versions of linezolid in India for as little as US\$ 8 per pill, amounting to an 88 percent discount in price. In June 2014, the South African Medicines Control Council (MCC) authorized MSF to import generic linezolid for use in its treatment programmes. This temporary measure is possible under Section 21 of the Medicines Control and Related Substances Act which allows for the sale of unregistered medicines for a specified amount of time and for a specific purpose. This has allowed MSF to obtain generic linezolid at Indian prices. Despite the fact the fact that Pfizer's patent on linezolid expired in August 2014, the delay in registering generic equivalents has left Pfizer as the only supplier of the medicine in the private sector, which enables it to continue charging inflated prices.

If the government's treatment program is to be sustainable in the long term, additional strategies to keep treatment costs low will be required. An application for the fast-track registration of a generic version of linezolid was submitted to the MCC in May 2013. Despite its own regulations requiring that an application for fast-track registration be completed within nine months, as of October 2014, the application had yet to be processed by the MCC.⁵⁴⁹

5.2.1 A profile of the South African Pharmaceutical manufacturing industry and the Role of Government

The South African pharmaceutical industry is the largest and the most advanced in Africa, with an estimated market value of US\$ 3.8 billion in 2011, expected to grow to US\$ 7 billion in 2018.⁵⁵⁰

⁵⁴⁹ According to a letter by a coalition of MSF doctors, people living with HIV and civil society activists to the Registrar of the MCC in South Africa. An electronic copy of the letter is [Online] Available: http://www.tbonline.info/media/uploads/documents/drtb_patients%2C_activists_demand_registering_generic_linezolid%2C_14.10.2014.pdf

⁵⁵⁰ See Press Release by Global Business Intelligence of 7 June 2012 entitled *South African Bid to Tackle AIDS Epidemic to Create National Pharmaceutical Market Boom* [Online] Available:

According to the National Association of Pharmaceutical Manufacturers (NAPM), the total value of sales in the South African private market for pharmaceuticals in 2013 was approximately US\$ 2 billion.⁵⁵¹ The South African pharmaceutical industry has also been identified as an important sector of the Industrial Policy Action Plan.⁵⁵² South African generic manufacturers also have a growing market share in other countries in the region. As far back as 2007, they accounted for more than 70 percent of the US\$ 1 billion in pharmaceuticals produced in the region.⁵⁵³ A profile of the local pharmaceutical manufacturers reveals a mix of research based and generic pharmaceutical manufacturers of which Aspen Pharmacare, a generic company is the largest, accounting for more than 16 percent of 2011 market share.⁵⁵⁴

Table 2: Ten Companies with the Largest Share of the South African Pharmaceutical Market

Rank	Company	Value in US\$ (Thousands)	Percentage of value
1	Aspen Pharmacare	408, 874	16.3
2	Adcock Ingram	245,392	9.8
3	Sanofi	190,751	7.6
4	Pfizer	160,758	6.4
5	Novartis	150,924	6
6	Cipla Medpro	121,844	4.9
7	Astra Zeneca	119,164	4.8
8	Johnson & Johnson	102,614	4.1
9	Merck	90,629	3.6
10	Roche	82,541	3.3

http://www.gbiresearch.com/pressreleasedetails.aspx?title=Pharmaceuticals_and_Healthcare&prid=38

⁵⁵¹ See a submission by the South African government to the Organization for Economic Co-operation (OECD) and Development on generic competition, Document number DAF/COMP/WD(2014)68.

⁵⁵² The IPAP is an industrial action plan compiled by the Department of Trade and Industry. It aims to promote diversification in the economy, promote a labour-absorbing industrialisation path, contribute to industrial development in other African countries, and facilitate a movement towards a knowledge economy.

⁵⁵³ IFC (2008) 'The business of health in Africa: Partnering with the private sector to improve people's lives' Washington DC: IFC, World Bank Group, [Online] Available:

http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/IFC_HealthinAfrica_Final.pdf

⁵⁵⁴ See 'Focus Reports (2012) Pharmaceutical South Africa Report 2012', Johannesburg, South Africa [Online] Available: http://issuu.com/focusreports/docs/pharmaceuticals_south_africa_report_2012

(Source) Pharmaceutical South Africa 2012 Report

There are two influential industry associations in the country. The Pharmaceutical Industry Association for South Africa (PAISA) has a membership of 18 predominantly research based companies, with a total of 25 percent of the South African pharmaceutical market. It represents South Africa on the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).⁵⁵⁵ The generic industry has the National Association of Pharmaceutical Manufacturers (NAPM)⁵⁵⁶ representing 90 percent of generic companies in the country, and 45 percent of its market share, a sign of the market dominance of Aspen Pharmacare, and Adcock Ingram who are not members of the NAPM. Aspen is not a member of either association, while Adcock Ingram has chosen to join PAISA.

Founded in South Africa in 1997, Aspen has grown to become now the largest generic pharmaceutical manufacturer in Africa with an extensive international network. The company now has a physical presence in 14 countries across Africa, Latin America, Europe and the Asia Pacific regions and supplies a combination of originator and generic medicines to more than 150 countries globally. It is now a top 10 generic manufacturer world-wide.⁵⁵⁷ Aspen has a close strategic relationship with several research based companies⁵⁵⁸ which includes the right to distribute GSK's pharmaceutical products in Africa, the acquisition of a GSK manufacturing facility in Germany and the issuing of 68.5 million shares to GSK. On intellectual property, Aspen's strategy has been to negotiate voluntary licenses with research based companies for the manufacture of ARVs, a measure undertaken with increased frequency as illustrated by the table below.

⁵⁵⁵ Among its list of shared values available on its website include a respect for intellectual property.

⁵⁵⁶ The NAPM was established in 1977 and is the longest standing trade association for the pharmaceutical industry in South Africa. Key among its objectives is to promote the use of generics, by increasing the market share and registration of generics by the MCC of South Africa.

⁵⁵⁷ See Aspen Pharmacare's website for additional information [Online] Available:

<http://www.aspenpharma.com/default.aspx?pid=9&stepid=1&oid=9>

⁵⁵⁸ For example, Aspen's commentary of the 2012 financial year ends results detail transactions with GSK, Pfizer, Novartis and Eli Lilly.

Table 3: List of Aspen Pharmacare's Voluntary Licenses to Produce ARVs

Patent holder	ARV	License Date	Royalty rate and conditions	Restrictions
GlaxoSmith-Kline (GSK)	lamivudine, zidovudine,	October 2001	Royalty of 30% on net sales	Public sector and not-for-profit organizations and charities in South Africa
	lamivudine+ zidovudine (3TC+AZT)	December 2003	Royalty not exceeding 5%	Public and private sector South Africa and Sub-Saharan Africa
	abacavir	July 2009	Royalty free	unclear
Boehringer Ingelheim (BI)	nevirapine	October 2002	15% royalty	Public and private Sector in SADC Region
	nevirapine	December 2003	Royalty not exceeding 5%	Public and private sector Sub-Saharan Africa
Bristol Myers Squibb (BMS)	stavudine (d4T),	July 2001	Immunity from suit	Public and private sectors in Africa
	didanosine (ddI)	August 2003	Licensing terms unknown	
	atazanavir (ATV)	February 2006	Non-exclusive, royalty-free technology transfer provision	World Bank Tier 1 designated countries (approximately 70 countries)
Gilead Sciences	tenofovir, tenofovir+ emtricitabine (TDF+FTC)	April 2005	Non-exclusive, 5% royalty, licensing and distribution agreement	Public and private system throughout Africa
Merck and co	efavirenz	July 2005	Non-exclusive, Royalty free	Public and private system in Sub-Saharan Africa
Hoffmann-La Roche	saquinavir (SQV)	September 2006	Non-exclusive, royalty-free with technology transfer provision	All Sub-Saharan Africa and other least-developed countries
Tibotec	Darunavir	April 2007	Distribution until demand requires manufacture	20 countries in Sub-Saharan Africa

	rilpivirine rilpivirine+ lamivudine	January 2011	Non-exclusive, Royalty of 2-5%	Sub-Saharan Africa
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Source: Wilson Kinsley R, (2009) and Knowledge Ecology International (2011)

The South African Government's policies have contributed to Aspen's growth. For instance, the Department of Trade and Industry (DTI) introduced a Strategic Investment Program to induce Aspen to invest US\$ 28.5 million in a manufacturing facility in the coastal city of Port Elizabeth to increase its pharmaceutical manufacturing capacity.⁵⁵⁹ As noted above, Aspen has expanded its presence into several countries including its acquisition of Shelys pharmaceuticals of Tanzania in recent years.

The two other South African pharmaceutical companies with significant market share in ARVs are Cipla Medpro and Adcock Ingram. Adcock Ingram is the larger of the two with a market capitalization of over US\$ 1 billion and occupies a 13 percent share of the generic pharmaceutical market. It has manufacturing plants in South Africa, India and Ghana.⁵⁶⁰ Cipla Medpro was established in South Africa in 1994 and accounted for 12.9 percent of the local generic market in 2011.⁵⁶¹ The company has invested more than US\$ 40 million into upgrading a Durban based pharmaceutical manufacturing facility, which includes continuous development, to international Pharmaceutical Inspection Co-operation Scheme Standards.⁵⁶²

Because of the size of its national ART programme, the decisions the South African Government makes regarding the procurement of medicines have a large impact on the domestic pharmaceutical industry. At the end of November 2012, the Department of Health released the outcome of a government tender contract⁵⁶³ for the supply of ARVs through the public healthcare system for

⁵⁵⁹ Interviews with Stavros Nicolaou (Aspen Pharmacare), 28 February 2006; 19 July 2006; and, 15 December 2006 as cited in Sprague C, & Woolman (2007) in 'A Case Study of Aspen Pharmacare' UNDP, New York [Online] Available: http://www.africa-platform.org/sites/default/files/resources/south_africa_aspen_pharmacare.pdf

⁵⁶⁰ See the company's website http://www.adcock.co.za/AboutUs_CompanyProfile.aspx for additional information

⁵⁶¹ According to the National Association of pharmaceutical manufacturers (NAPM).

⁵⁶² See <http://www.ciplamedsa.co.za/> for more information.

⁵⁶³ Issued in accordance with Chapter 16 A of the Treasury Regulations published in terms of the Public Finance Management Act 1 of 1999.

2013-2014, valued at almost US\$ 670 million. Cipla-Medpro was awarded 25 percent of the total value of the tender, while Aspen Pharmacare and Adcock Ingram were awarded 20.6 percent and 14 percent of the tender respectively.⁵⁶⁴

In recent years, the South African Government has begun to develop a public sector strategy around drug manufacturing. Citing the country high burden of disease, the projection that the number of patients who will be on treatment through public sector programs will rise to between 3.5 and 3.7 million people by the year 2017, and the rise in treatment costs,⁵⁶⁵ the Government announced in 2011, its intention to develop the pharmaceutical sector as part of its industrial policy strategy.⁵⁶⁶ The Government also views the development of a local pharmaceutical industry as a way to reduce the import burden of medical products (defined as pharmaceuticals, medical diagnostics and devices), currently the fifth largest contributor to the country's import burden. The government has noted with concern that importing 95 percent of APIs for ARVs and antibiotics is *“a precarious situation considering the level of AIDS and TB epidemics in South Africa and the region.”*⁵⁶⁷ The government strategy intends to produce 500 tons of APIs per annum by 2016, which amounts to 40 percent of projected needs.⁵⁶⁸

In February 2012, the South African Government announced an initiative named “Ketlaphela” (which in the local language of Sesotho translates to “I will live or survive”) between a government subsidiary Pelchem⁵⁶⁹(pty) Ltd and the Swiss pharmaceutical company Lonza Ltd. The joint venture was to have established a plant to manufacture APIs in South Africa. A few months later,

⁵⁶⁴ The full details of the tender including the types of ARVs, dosages and prices are available from the Department of Health circular dated 29 November 2012 [Online] Available: http://www.doh.gov.za/docs/contracts/2012/hp13_2o13arv.pdf

⁵⁶⁵ According to estimates from the National Treasury medium term estimates in the industrial policy action plan, the cost of pharmaceutical procurements will exceed US\$ 1 billion for the 2013/2014 financial year. See Department of Trade and Industry (2010) ‘Industrial Policy Action Plan 2013/13-2014/15’ [Online] Available: <http://www.info.gov.za/view/DownloadFileAction?id=162797>

⁵⁶⁶ More details on the development of a pharmaceutical manufacturing industry are found on pg. 87-92.

⁵⁶⁷ Ibid at 88.

⁵⁶⁸ Ibid at 90.

⁵⁶⁹ Pelchem Ltd is a subsidiary of The South African Nuclear Energy Corporation whose purpose is to maintain and grow the portfolio of fluorochemical businesses as envisaged by the national industrial policy Action plan and to support the South African Fluorochemical Expansion Initiative.

the Lonza Ltd withdrew from the project citing commercial concerns.⁵⁷⁰ The South African government quickly announced its intention to search for a new partner.⁵⁷¹ The total planned investment in Ketlaphela was approximately US\$ 180 million, two thirds of which is funded by various South African state institutions.⁵⁷² The initiative will initially focus on alleviating the disease burden of HIV and TB but will eventually also address the manufacturing of APIs for NCDs. The modalities and incentives required to ensure the sustainability of the Ketlaphela project will be determined by an inter-departmental task team comprising the Departments of Science and Technology, Trade and Industry, Economic Development, Health, and Energy, under the leadership of the Department of Science and Technology which suggests a degree of inter-departmental coherence or co-operation.⁵⁷³

However, as will be discussed in chapter six, the Department of Science and Technology has been actively involved in initiatives at the continental level, which if successful, would increase the level of intellectual property protection and enforcement among African countries. This raises the question of whether all the Government departments participating in the initiative are aligned as to what the most appropriate intellectual property policy would be for both the Ketlaphela project and the sustainability of treatment programmes countrywide. While the viability initiative relies on a variety of factors, the Government's intellectual property policy and the retention of policy space available under the TRIPS Agreement will play an important role. Intellectual property legislation and policy relevant to access to treatment in South Africa is discussed below.

5.3 South African Intellectual Property Legislation Institutions and Practices: What Impact on a Sustainable Supply of Treatment

As discussed above, South Africa's generic pharmaceutical industry has developed rapidly, making inroads into the continent and in some cases, forging strategic alliances with originator

⁵⁷⁰ According to a News Report of 22 May 2013 *Swiss Company Pulls Out of SA Pharmaceutical Company* [Online] Available: <http://www.ventures-africa.com/2013/05/swiss-investor-pulls-out-of-sa-pharmaceutical-company/>

⁵⁷¹ Ibid.

⁵⁷² As per the 12 February 2012 media statement by the South African Government on the establishment of a pharmaceutical manufacturing plant in South Africa [Online] Available: <http://www.info.gov.za/speech/DynamicAction?pageid=461&sid=24995&tid=56037>

⁵⁷³ Ibid.

companies. These alliances have been instrumental in expanding the types of health technologies it has been able to produce. The legislative and regulatory framework have not kept up with the pace of developments in the private sector given that the last significant reform of the Patents Act in South Africa took place shortly after the TRIPS Agreement came into force. This delay in overhauling the legislative framework raises questions regarding the capacity within the relevant government departments to fully integrate and use public health related TRIPS flexibilities. Moreover, as highlighted in the third hypothesis in chapter one, policy incoherence or misalignment among governmental institutions responsible for the implementation of intellectual property policy may undermine the incorporation or use of public health related TRIPS flexibilities. Various provisions found in the Patent Act, Counterfeit Goods Act, Intellectual Property Rights from Publicly Funded Research and Development Act and Medicines and Related Substances Control Act all have an impact on the sustainable supply of treatment for HIV, its co-infections and NCDs in South Africa.

The formal history of intellectual property legislation in South Africa dates back to the Patents, Designs, Trade Marks, and Copyright Act of 1916.⁵⁷⁴ When the 1916 Act was eventually repealed, each of the various intellectual property subjects was dealt with under separate pieces of legislation.⁵⁷⁵ South Africa joined WIPO in 1975 and embarked on reforming patent, plant breeding and copyright legislation soon after.⁵⁷⁶ Another wave of legislative amendments followed after the establishment of the WTO in 1995.⁵⁷⁷ South Africa then acceded to the Patent Cooperation Treaty (PCT) in 1999.⁵⁷⁸ Since then, there has not been a regular process of law reform to comply with developments in international treaties and shifting development priorities and objectives such as the development of a local manufacturing industry.

⁵⁷⁴ See Teljeur E, (2003) 'Intellectual Property Rights in South Africa: An Economic Review of Policy and Impact', The Edge Institute, South Africa.

⁵⁷⁵ Burrell T, (1999) "Burrell's South African Patent and Design's Law" 3rd Edition, Butterworth's, Durban, South Africa.

⁵⁷⁶ The Plant Improvement Act 53 of 1976, the Copyright and Patent Acts both passed in 1978.

⁵⁷⁷ Such as the Intellectual property rationalization Act 107 of 1996, Intellectual Property Laws Amendment Act of 1997, the Genetically Modified Organisms Act 15 of 1997 and the Medicines and Related Substances Control Act of 1997.

⁵⁷⁸ According to WIPO, South Africa deposited its instrument of accession to the PCT on December 16, 1998 which came into effect in March 1999.

As noted above, extensive legislative reform has not taken place to incorporate public health related TRIPS flexibilities into national legislation. The DTI is undertaking an additional phase of intellectual property related legislative review and had been developing a new intellectual property policy since 2012,⁵⁷⁹ culminating in the publication of the draft in the Government Gazette in September 2013. The draft policy once adopted should eventually result in the reform of intellectual property legislation across a variety of subject matter including patents. The current policy makes some important proposals incorporating additional public health related TRIPS flexibilities. These include the strengthening of provisions relating to compulsory licensing and patent oppositions. Most significantly, the draft policy recommends that the government give serious consideration to establishing a substantive patent examination system.⁵⁸⁰ The DTI invited interested parties to submit their comments to the draft policy which prompted a plethora of submissions from both within and outside of the country. More than 100 submissions were received before the deadline from various stakeholders ranging from treatment activists, members of academia, industry associations within and outside of the country, United Nations entities, and even the European Union.⁵⁸¹

Controversy broke a few months later when a leaked email⁵⁸² exposing a plot by the originator pharmaceutical industry to delay the adoption of the policy and the removal of public health related recommendations found in the draft policy was uncovered in January 2014. The email which noted among other things, that:

“...South Africa is now ground zero for the debate on the value of strong intellectual property protection. If the battle is lost here, the effects will resonate... Without a vigorous campaign, opponents of strong intellectual property will prevail – not just in South Africa, but eventually in much of the rest of the developing world.”

⁵⁷⁹ According to Minister of Trade and Industry Rob Davies in a speech given at the Africa Intellectual Property Forum hosted by the Department of Trade and Industry in Johannesburg on 27 February 2013. The draft policy was published in the Government Gazette in September 2013.

⁵⁸⁰ An electronic copy of the draft policy is [Online] Available:

http://groundup.org.za/sites/default/files/36816_gen918.pdf

⁵⁸¹ See IP Watch Article of 18 November 2013 entitled *Comments Received on South Africa's Process for New IP Policy* [Online] Available: <http://www.ip-watch.org/2013/11/18/comments-received-to-south-africas-process-for-new-ip-policy/>

⁵⁸² The full text of the email is [Online] Available: <http://keionline.org/sites/default/files/merck-email.pdf>

The plot evoked a strong response from both the South African government and civil society groups.⁵⁸³ South Africa also has observer status at ARIPO.⁵⁸⁴ According to World Bank country classification system, South Africa is an Upper Middle Income Country (UMIC)⁵⁸⁵ According to its GDP, South Africa accounts for approximately a third of the entire sub-Saharan African economy.⁵⁸⁶ Yet, a closer look at the levels of domestic innovation reveal surprisingly low numbers of patent applications filed by local people and companies.

A 2011 study which examined the quantity and quality of patents granted by the industrial property offices⁵⁸⁷ of Argentina, Brazil, Colombia, India and South Africa found that the vast majority of patents being granted in all of these countries are of developed country origin. According to the research, in Argentina, of the 951 pharmaceutical patents granted from the period 2000-2007, only 15 were granted to nationals (eight companies, one research institute and 5 individuals). In Brazil, 278 patents were granted in 2003-2008 of which only one was granted to a Brazilian pharmaceutical manufacturer. Of the 439 pharmaceutical patents granted in Colombia in the period between 2004 and 2008, only two were granted to local applicants. In the case of South Africa, even though 2442 patents were registered by the then Companies and Intellectual Property Registration Office (CIPRO) in 2008 alone, only 10 patents were registered by local companies, research institutions or individuals, amounting to less than a tenth of a percent.⁵⁸⁸ These data raise serious questions around the rationale of having laws that do not provide for substantive patent

⁵⁸³ A news article dated 22 January 2014 by IP Watch quoted the Minister of Trade Rob Davies as saying “*This is a lobby attempt and it’s envisioning a few dirty tricks.... This is to take it outside the realm of a normal democratic debate*” while an incensed Minister of Health was quoted in the Mail and Guardian Newspaper of 16 January 2014 referring to the plot as ‘genocide’ and a plot of ‘satanic magnitude.’ The reactions by MSF and Section 27 are [Online] Available: <http://www.fixthepatentlaws.org/?p=823>

⁵⁸⁴ As provided for under Article VI of the Lusaka Agreement of 1976 which allows the organization to liaise with non-Member States. South Africa’s observer status means that it is regarded as a potential member of ARIPO.

⁵⁸⁵ By the World Bank, based per capita income. The income bracket to be considered as an UMIC is US\$ 4, 036 to US\$ 12, 475.

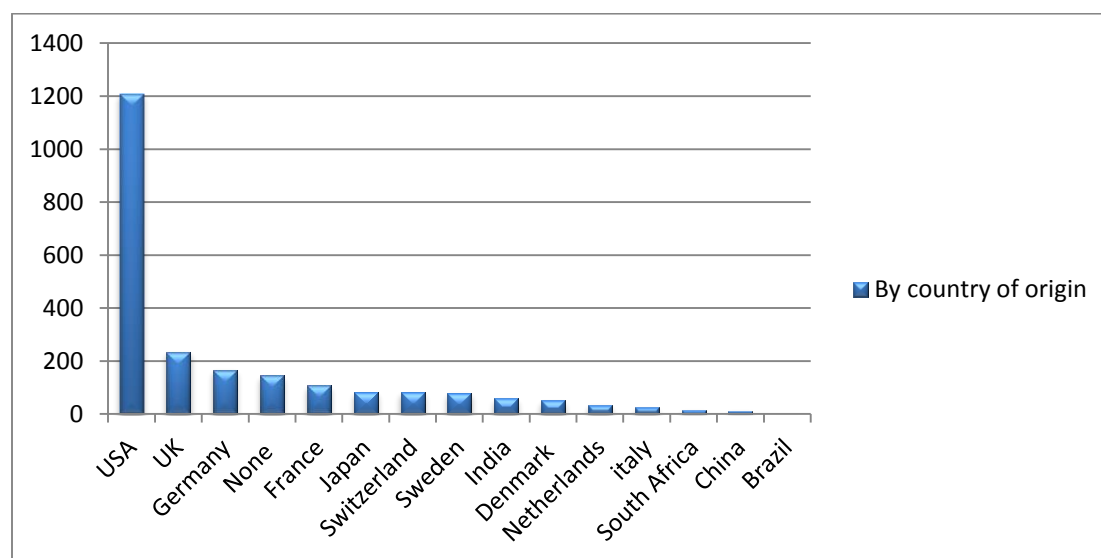
⁵⁸⁶ International Monetary Fund (IMF) (2012) ‘Regional Economic Outlook: Sub Saharan Africa’ IMF, Washington D.C. [Online] Available: <http://www.imf.org/external/pubs/ft/reo/2012/afr/eng/sreo1012.pdf>

⁵⁸⁷ Correa C, (2011) ‘Pharmaceutical innovation, Incremental Patenting and Compulsory Licensing’, South Centre, Research Paper 41, Geneva at 7.

⁵⁸⁸ The vast majority of patent applications came from the US certain European countries (Belgium, France, Germany, Italy, Netherlands, Switzerland, the UK) and Japan. See Vawda Y, (2011) ‘Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing Case Study: South Africa’ on file with author.

examination.⁵⁸⁹ Tellingly, despite the size and comparative complexity of its economy, South Africa does not have a patent office that conducts substantive pharmaceutical patent examinations. The absence of a substantive patent examination system appears to seriously undermine both the industrial policy objectives of stimulating local pharmaceutical production and maintaining sustainable treatment programmes.

Figure 3: Nationality of Patent Holders in South Africa in 2008



Source: Vawda, Y 2011

5.3.1 Patent Oppositions, Revocations and Substantive Examinations

As noted above in Chapter four, the TRIPS Agreement is silent on the issue of patent oppositions. Several countries⁵⁹⁰ provide for patent oppositions to be filed either before or after the grant of a patent as a way of adding an additional layer of rigour to the granting of patents which meet the

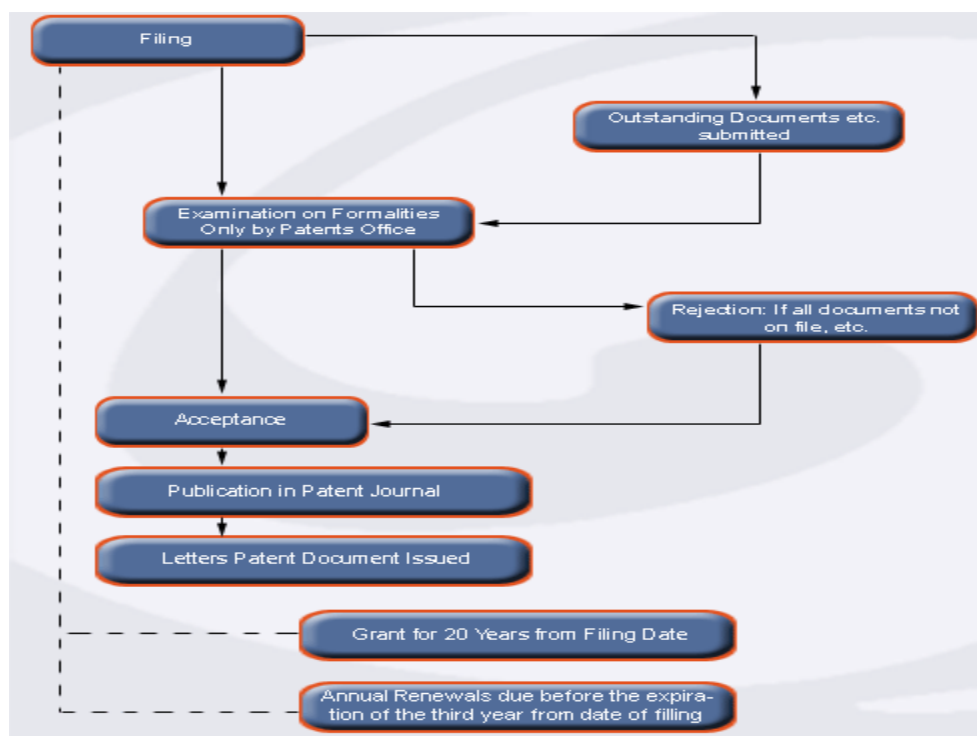
⁵⁸⁹ Further analysis of the data shows that in 2012, 685 patents were granted to local entities and individuals while 5520 patents were granted to foreign entities and individuals at the same time.

⁵⁹⁰ For instance Article 100 of the European Patent Convention (EPC) allows any person to file an opposition within 9 months of publication of the patent on a number of grounds including insufficient disclosure of the method of invention, that the subject matter of the patent is actually not patentable as per the requirements of the EPC or that the subject matter extends beyond the content of the patent application. Several other countries including Australia, Brazil, Egypt, Japan and India also provide for patent oppositions. For more information, see a document prepared by WIPO (2010) 'Opposition Systems' Standing Committee on the Law of Patents, Fourteenth session [Online] Available: http://www.wipo.int/edocs/mdocs/scp/en/scp_14/scp_14_5.pdf

required levels of novelty, inventiveness and utility. The challenges posed by the fact that South African patent authorities do not substantively examine applications are further amplified by the fact that the Patents Act does not provide for patent oppositions before patents are registered. The institution that fulfils the roles and functions of a patent office is the Companies and Intellectual Property Commission, (CIPC) launched in 2011 and housed within the Department of Trade and Industry, does not conduct substantive examinations of patent applications. Instead, patent applications are reviewed and either approved or rejected on the basis of their compliance with formal requirements. The process of obtaining a South African patent includes a three step procedure comprising of:

- (i) The conducting of an initial search by the patent applicant to or a representative to ensure that the application will not infringe on an existing patent and meets the requirement of novelty
- (ii) Applying for the registration of a patent (either through a provisional or complete application, or through the Patent Cooperation Treaty); and
- (iii) A process of formal examination which takes approximately six months after the patent application has been received.

Figure 4: The Patent Registration Process in South Africa



Source: South African Companies and Intellectual Commission (CIPC)

Given the comparative complexity of South Africa's economy, manufacturing base and industrial policy objectives, the absence of an office that substantively examines pharmaceutical patents remains a serious shortfall in the government's plans to sustain its treatment programs. The lack of a substantive patent examination system and legislation that takes full advantage of the policy space available under Article 27 of TRIPS is amplified by an example found in a briefing note prepared by TAC, MSF and Research and Information Systems for Developing Countries (RIS). According to the note, that several patents on the third line ARV darunavir, for which the first global patent was filed in 1983 have extended the patent life of the medicine in South Africa to 2028. By contrast, darunavir was not eligible for patent protection in India in 1993 because the country did not allow pharmaceutical products to be patented. After the 2005 Patents Amendments Act was enacted, subsequent patent applications for new forms of darunavir were rejected by the Indian patent office in light of Section 3(d) of the Act, with the result that generic darunavir became available in India at a comparatively early stage.⁵⁹¹ This example highlights both the importance

⁵⁹¹ See TAC, RIS, MSF (2013) 'Why South Africa Should Examine Pharmaceutical Patents', Briefing Note [Online] Available: http://www.msfaaccess.org/sites/default/files/MSF_assets/Access/Docs/Access_Brief_SApharmap atents_ENG_2013_final.pdf

of establishing a substantive examination system and having comparatively strict criteria for patentability as part of a public health sensitive strategy.

There is no explicit provision authorizing patent oppositions in South Africa's Act. The lack of an expedient and accessible patent opposition provision is compounded by the potential expense and length of litigation to revoke a questionable patent. According to legal experts, it has been estimated that on average it could take up to three years to fully litigate the validity of a single patent in proceedings before the patent commissioner.⁵⁹²

The Act provides a limited number of instances⁵⁹³ under which a patent may be revoked including the following:

- The applicant is neither the inventor or a legally assigned representative;
- The grant would be in fraud of the rights of the applicant or otherwise contains a false statement;
- The applicant is not patentable (including that it does not meet the criteria contained in Section 27 requiring an invention to be new, contain an inventive step and be capable of industrial or agricultural applicability;
- Insufficient or incorrect disclosure of the method of invention in the patent claim resulting in a person skilled in the art being unable to make the invention; and
- Frivolity or an invention that is against the public interest.

While these grounds may benefit from further refinement or definition, the real barriers to greater use of patent revocation proceedings include the absence of patent examiners at Department of Trade and Industry who, if present, could have acted both as examiners *ab initio* in the ordinary conducting of their responsibilities, and who could have also been participants of an administrative board to hear technical arguments about the validity of patents instead of judges who may not necessarily have the same depth of expertise. The second key impediment is the set of onerous

⁵⁹² Ibid Park, Prabhala and Berger at 54.

⁵⁹³ Including fraud as per Section 63, even though it remains possible for the inventor or his assignee to be re-awarded a patent even after revocation on the grounds of fraud, or voluntary surrender, as per section 64 of the Act.

procedural requirements contained in the Act⁵⁹⁴ which, in essence, turn any hearing presided over by the patent commissioner into a judicial proceeding. For example, Section 19 (1) of the Act requires that:

“Save as is otherwise provided in this Act, the procedure in connection with any proceedings before the commissioner shall, as far as practicable, be in accordance with the law governing procedure in civil cases in the Transvaal Provincial Division of the Supreme Court of South Africa...”

In addition, Section 19(3) of the Act requires a party to any proceedings presided over by a patent commissioner to be an attorney, patent agent or advocate of the High Court of South Africa. The third impediment concerns the general lack of information around patent claims. Section 42 of the Act only requires that information about a patent be published after it is granted.⁵⁹⁵ Requiring the publishing of information when the patent application is filed could have implications for treatment access. Interested parties could be provided with the opportunity to participate in patent oppositions. This may be particularly important in South Africa where judicial precedent reflects a reluctance on the part of the Courts to revoke patents.⁵⁹⁶

There are a variety of policy options⁵⁹⁷ under the current Patent Act which would make patent oppositions less onerous. The most important step would be to move the patent application system away from registration to one where substantive examinations are undertaken. While the thought of establishing an office that examines thousands of patents every year may appear daunting,⁵⁹⁸ an

⁵⁹⁴ Further elaborated upon in Sections 18 and 19.

⁵⁹⁵ The relevant portions of Section 42 read as follows:

- (1) *When a complete specification has been accepted, the registrar shall give written notice of that fact to the applicant.*
- (2) *Such notice shall contain—*
 - (a) *the date of acceptance of the specification; and*
 - (b) *a statement that on publication by the applicant in the journal of the acceptance of the specification, the patent concerned shall be deemed to have been sealed and granted as from the date of such publication.*

⁵⁹⁶ In the case of *Pfizer & Another v Cipla Medpro & Others* 2005 BIP 1, the Court refused to revoke, accepting that the besylate salt was itself unexpected, constituted an advance on the prior art, and represented an inventive step forward.

⁵⁹⁷ See Park, Prabhala and Berger at 52-55 for a discussion of possible remedies available to authorities.

⁵⁹⁸ According to information obtained from WIPO, more than 7440 patent applications were filed in South Africa in 2012.

interim measure could be the adoption of an examination system for patent applications involving certain sectors such as pharmaceuticals. An even more plausible starting point could be to only subject applications for pharmaceuticals important to meet broader government public health objectives to patent examination, and to focus on applications for pharmaceutical products used to treat AIDS, TB, viral hepatitis and key NCDs. The job of potential patent examiners could be made easier by the inclusion of TRIPS flexibilities such as imposing a duty on the applicant to disclose the best method of carrying out the invention.

Other ways to facilitate patent oppositions include the providing of clear and explicit provisions for pre and post- grant patent oppositions complete with broad grounds under which they may activated or used. Broadening the scope of interested parties to include civil society and government is another option.⁵⁹⁹ Another important addition to patent opposition provisions includes the setting of timelines under which such oppositions should take place. For instance, the Brazilian Industrial Property Law⁶⁰⁰ requires the INPI upon accepting a request for a patent nullification, to give the patent applicant and the person who filed the opposition 60 days to make written representations. The law also requires the president of INPI to make a decision regarding the validity of the patent law within an additional 60 days.⁶⁰¹ Egypt's law gives even stricter timelines and gives a specially constituted administrative committee 60 days from when the opposition was filed to make a decision on the validity of the patent application.

Patent opposition or revocation proceedings could also be simplified by replacing the judicial proceedings presided over by the patent controller with an administrative or quasi-judicial body which operate in a more informal matter. This should make patent oppositions easier, faster and less expensive to use than the current revocation proceedings under the Patent Act. In addition, the patent commissioner could be replaced with an administrative body that includes people with practical expertise and a sound technical knowledge of the subject matter at hand. In India, patent oppositions are first heard by patent controller. In Brazil, the final decision regarding the success

⁵⁹⁹ For example, Egypt's law on the protection of Intellectual Property Rights (Law 82 of 2002) allows the relevant government department under whose jurisdiction the subject matter of the patent application falls, to oppose the application within 90 days from the publication of the patent application.

⁶⁰⁰ Law 9.279 of 1996.

⁶⁰¹ As per Articles 53 and 54 of the law.

of a patent opposition lies with the head of the INPI, while in India, the Patent Controller after considering evidence from both parties, is responsible for deciding on the success of a pre or post grant patent opposition.⁶⁰² Finally, a key concern should be to keep proceedings as expedient as possible and to prevent the unnecessary delay of the outcome of patent oppositions, including the strategic use of judicial systems to delay the outcome of a patent opposition.

5.3.2 Patentability Criteria and Exclusion from Patentability

Aside from moving away from a system of patent registration to a substantive examination system and providing for more explicit, broader and expedient patent opposition provisions in the Patent Act, other policy levers that merit closer attention by South African authorities are the criteria for patentability. As discussed above in chapter four, the TRIPS Agreement provides WTO Members significant latitude to further define criteria for patentability in their national patent legislation.

In deciding what approach to take, a country like South Africa may wish to consider a variety of factors including the innovative capacity of its manufacturing industry in key sectors of agriculture and pharmaceuticals as well as the extent to which local innovators make use of the patent system. While recent data indicates that South Africa pharmaceutical companies accounted for almost 40 percent of the local market in 2010, the bulk of market presence related to generic medicines, in particular, ARVs. As discussed in chapter two, there is increasing evidence that the granting of patents for incremental innovation can stifle rather than incentivise it. In determining its policy on patentability criteria, the question as to the quality of patents being granted and whether they are helping to stimulate innovation remains an important consideration.

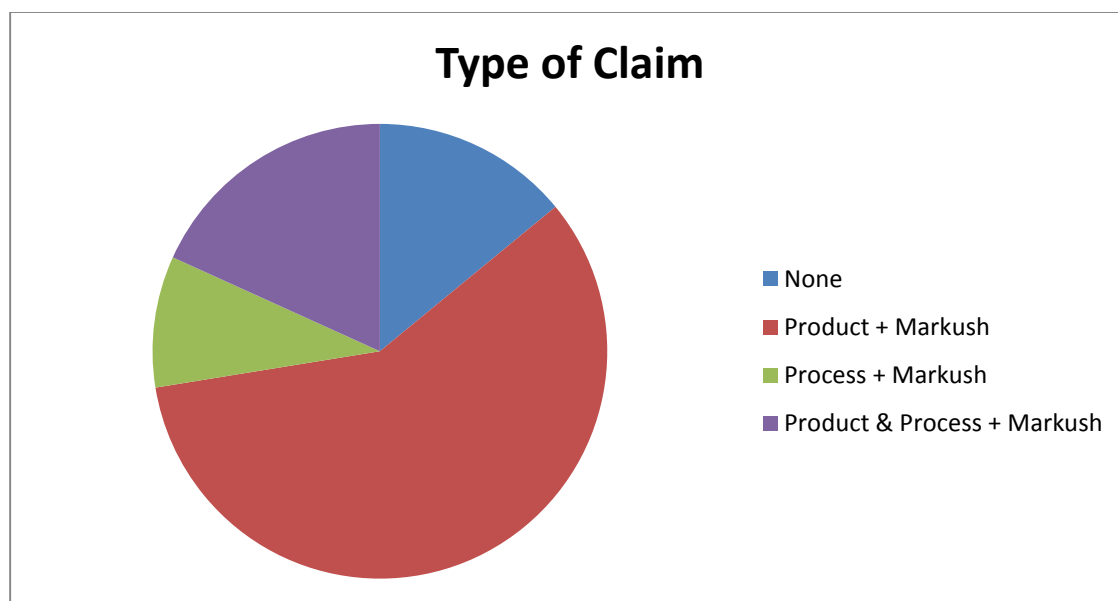
Government policy on this matter should be determined by whether the registered patents reward genuine innovation or are examples of ever greening. An analysis of the pharmaceutical patents registered in South Africa in 2008 indicates that the majority of them were so called Markush claims, which essentially are claims that include broad or general formulae with multiple options

⁶⁰² Section 25(4) of the Patents Act 1970.

that allow for the protection, under a single patent, of up to several millions molecules.⁶⁰³ This is problematic for reasons elaborated upon by Correa below:

*“Markush claims raise issues concerning sufficiency of disclosure, since normally the patent applicant has empirically obtained only a few of the multiple claimed compounds. In addition, it is virtually impossible to make prior art searches for thousands or millions of compounds. They also pose a transparency problem, since it is very difficult for third parties to identify patent applications that would merit a pre or post-grant opposition.”*⁶⁰⁴

Figure 5: Distribution of pharmaceutical patents in South Africa 2008 by claim



Source Vawda (2011)

Another factor that may inform a country's decision to set strict or lax criteria for patentability is the extent to which local innovators make use of the patent system. Given that South African individuals and companies accounted for less than a percent of pharmaceutical patent registrations in South Africa in 2008, and considering that policies that encourage generic competition are

⁶⁰³ Ibid Correa at 12. As elaborated upon, Dr. Markush was the founder and head of a pharma-chemical in the US and was a leading manufacturer of dyes. Dr. Markush had over 20 patents on synthetic dyes and related fields. In 1924, Dr. Markush obtained a patent on pyrazolone-based dyes (U.S. No. 1,506,316) which protected a generic chemical structure, in addition to the products already synthesized. Since then patenting of such structures have been allowed in the US.

⁶⁰⁴ Ibid Correa at 13.

advantageous regarding the sustainability of its national AIDS treatment program, it follows that a policy that allows patents to be granted only where genuine contributions to the state of the art are made, would be the most desirable one for South Africa at this stage. It also follows that the success of patent claims that relate to incremental innovation, second indications of pharmaceutical products and selection patents on a narrow gap of molecular compounds should be minimized. The three criteria of novelty, inventive step and industrial applicability as found in the South African Patent Act are briefly discussed below:

(i) Novelty

According to Section 25 (1) of the Patent Act:

“A patent may, subject to the provisions of this section, be granted for any new invention which involves an inventive step and which is capable of being used or applied in trade or industry or agriculture.”

The definition of novelty or what is considered to be a new invention is elaborated upon in the Section 25(5) which notes that:

“An invention shall be deemed to be new if it does not form part of the state of the art immediately before the priority date of any claim to that invention.”

On the face of it, the Patent Act contains a public health sensitive reading of the concept novelty by having a requirement of absolute novelty. Section 25(6) describes the state of the art to comprise all matter made available to the public anywhere in the world, through written, oral description or any other use. This increases the requirement on the patent applicant to demonstrate genuine innovation. Section 25(8) for instance also notes that an invention used secretly and on a commercial scale shall be considered to form part of the state of the art. From a public health perspective, the high standard of novelty is to some degree undermined by the contents of Section 25(9) which reads as follows:

“In the case of an invention consisting of a substance or composition for use in a method of treatment of the human or animal body by surgery or therapy or of diagnosis practised on the human or animal body, the fact that the substance or composition forms part of the state of the art immediately before the priority date of the invention shall not prevent a patent being granted for the invention if the use of the substance or composition in any such method does not form part of the state of the art at that date.”

The impact of Section 25(9) is that the requirement of novelty can be satisfied even if a substance was already known provided the particular medical or therapeutic use for that substance had not been known. This greatly expands the possibility to register new patents on pharmaceutical products that are not only known, but already on the market.⁶⁰⁵ Park Prabhala and Berger⁶⁰⁶ also highlight the possible consequences of adopting narrow definition of novelty, which is the possibility of obtaining additional patents for the same technology over a period of time through the filing of selection patents,⁶⁰⁷ thereby prolonging the period of patent exclusivity. The addition of a provision explicitly precluding the selection of a sub-set of existing molecules from patentability would give further effect to the principle of absolute novelty.

(ii) Inventive Step

As discussed above in Chapter four, the requirement under Article 27.1 of TRIPS that a patent contain an inventive step has been applied in different ways by countries depending on their policy objectives. For developing countries whose priority should be to reduce the eligibility of incremental innovations to be granted patents,⁶⁰⁸ a high level of inventive step would be more advantageous.

According to the relevant portion of Section 25(10) of the Patents Act:

⁶⁰⁵ Park, Prabhala and Berger at 29.

⁶⁰⁶ Ibid at 28.

⁶⁰⁷ It is common practice for pharmaceutical companies to initially file patent applications on as broad a range of molecules and compounds as possible, and as the period of patent exclusivity draws to a close, to select a sub-set of compounds for a subsequent patent application.

⁶⁰⁸ Ibid Correa 2007.

“...an invention shall be deemed to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms, immediately before the priority date of the invention, part of the state of the art...”

While Section 25(10) refers to “a person skilled in the art” there is no elaboration on whether such person should be ordinarily or highly skilled. One of the key criteria in evaluating the inventive step criterion is what a person skilled in the art (such as a person trained and experienced in pharmaceutical formulation) could consider the invention obvious in the light of such prior art. The theoretical rationale here is that a pharmaceutical patent examiner who is highly skilled and hypothetically speaking, has twenty years of experience working in a pharmaceutical laboratory and a PhD in the field of molecular chemistry is likely to consider a greater number of pharmaceutical patent claims to be obvious and consequently not patentable as compared, for example, with a patent examiner with a Bachelor’s degree in physics with two years of relevant work experience. The South African Courts⁶⁰⁹ have given some interpretation to the term “*skilled in the art*” and have proposed that an enquiry focusing on what the art or science to which the patent relates is, who the person skilled in the art is and what the state of the art at the relevant date was, are key elements in determining inventive step. Regardless of the interpretation of the term provided by the Court, it goes without saying that raising the requirement to a person highly skilled in the art is likely to increase the threshold for patentability as the patent examiner would be more likely to consider selection patents or new uses of known substances to be obvious.

(iii) Exclusion from patentability

As noted above in chapter four, Articles 27.2 and 27.3 of the TRIPS Agreement provide WTO Members with the additional flexibility to exclude certain products from patentability. Article 27.2 reads as follows:

“Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment,

⁶⁰⁹ See for instance, Ensign-Bickford, Ltd. V. AECI Explosives & Chemicals Ltd, 1999 (1) SA 70 (SCA) at 80.

provided that such exclusion is not made merely because the exploitation is prohibited by their law.”

While the Patents Act contains a provision which gives some effect to Article 27.2 of TRIPS, Section 25 (4) does not take full advantage of the policy space provided by TRIPS. Section 25(4)(a) notes that:

“A patent shall not be granted

(a) for an invention the publication or exploitation of which would be generally expected to encourage offensive or immoral behaviour”

The narrow wording of Section 24(4)(a) means that patents can only be excluded from patentability for moral grounds whereas Article 27.2 of TRIPS allows the exclusion of certain subject matter as may be necessary to protect human animal or plant life or to protect public order. The Act could be made more sensitive to public health concerns with the inclusion of a provision expressly limiting from patentability, new uses on existing or known substances regardless of how the patent claim is drafted, which is the essence of Section 3(d) of the Indian Patents Amendment Act of 2005. The validity of Section 3(d) was affirmed by the Indian Supreme Court in April 2013 in its endorsement of the decision of the Patent Controller of India to reject a patent application by Novartis on the beta-crystalline form of imatinib mesylate, a drug used to treat chronic myeloid leukaemia and other tumours.⁶¹⁰ The affirmation of the Indian government’s prerogative to provide a public health sensitive interpretation of Article 27 of TRIPS as a means of keeping the cost of treatment affordable, coupled with the strategic interests of the South African Government in investing in a domestic pharmaceutical manufacturing industry, make compelling arguments for the adoption of a similar clause in the South African Patents Act.

⁶¹⁰ The basic molecule, imatinib, had been discovered in the early 1990s and according to the Court, should not be patentable because of trifling changes to it. See *Novartis AG vs. Union of India and Others*, Supreme Court of India, Civil Appeal Nos. 2706-2716 of 201, 1 April 2013

5.3.3 Duration of Patents, Disclosure Requirements, Exhaustion of Rights and General Exceptions

(i) Patent term durations and Disclosure requirements

Article 33 of the TRIPS Agreement requires WTO Members to provide a minimum period of 20 years patent protection,⁶¹¹ which appears to be the language adopted in Section 46 of the Patent Act. However, as described above, the impact of not strategically defining the criteria for patentability or the exclusion of certain subject matter from patentability can result in the extension of the patent term through for instance, the process of filing Markush claims selection patents. The 20 year period of patent duration is subject to the patent being maintained in accordance with Section 46(2).⁶¹² According to an experienced South African patent attorney, more than two thirds of patents registered in South Africa expire well before the 20 year period of patent exclusivity elapses because maintenance fees are not paid.⁶¹³

As discussed above in Chapter four, Article 29 of the TRIPS Agreement obliges WTO Members to require that the applicant disclose the invention in a manner that is sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Members may also require applicants to disclose the best mode of invention known to the inventor at the filing date.⁶¹⁴ The important discretion is provided to WTO Members to require a patent applicant to provide information regarding corresponding patent applications and grants in other countries.⁶¹⁵ Article 29 of TRIPS provides two important opportunities for the South African policy makers for two reasons: First, for a country interested in strengthening its local pharmaceutical industry, the requirement for the disclosure of best mode of carrying out the invention provides a policy avenue to promote the transfer of technology from the innovator to others, be they state owned or private sector. Second, for a country with a patent registration system that should be moving towards the

⁶¹¹ The 20 years is counted from the date of filing.

⁶¹² According to Section 46(2):

“A patent shall lapse at the end of the period prescribed for the payment of any prescribed renewal fee, if it is not paid within that period: Provided that the registrar may upon application and subject to the payment of such additional fee as may be prescribed, extend the period for payment of any such fee for a period not exceeding six months.”

⁶¹³ Statements by Dani Dohmen of the law firm Adams and Adams at the IP forum hosted by the South African Department of Trade and Industry in Johannesburg on 27 February 2013.

⁶¹⁴ As per Article 29.1 of TRIPS.

⁶¹⁵ See Article 29.2 of TRIPS.

substantive examination of pharmaceutical patents, imposing a requirement for a patent applicant to disclose the status of patent claims in other jurisdictions can be instructive in applying the novelty requirement for patentability criteria. This information could also be of invaluable use to patent examiners in determining whether countries with similar criteria for novelty, inventive step and industrial applicability have accepted or rejected patent claims similar to those filed in South Africa.

The relevant section of the Patents Act giving effect to Article 29.1 is Section 32(3) which requires a complete patent claim to:

*“(a) have an abstract as prescribed;
(b) sufficiently describe, ascertain and, where necessary, illustrate or exemplify the invention and the manner in which it is to be performed in order to enable the invention to be performed by a person skilled in the art of such invention; and
(d) end with a claim or claims defining the invention for which protection is claimed.”*

While Section 32(3) requires disclosure sufficient to allow the carrying out of the invention to allow performance by a person skilled in the art, the failure to include a requirement to disclose the best mode of carrying out an invention continues to provide the inventor with a comparative advantage even after the expiry of the patent. Some would argue that Section 32(3) undermines the basic social contract between an inventor and society in terms of which the former is granted a period of temporary exclusivity in exchange for the technological advancement of society.⁶¹⁶ Moreover, the Patent Act does not contain any provisions requiring that information relating to the status of patent applications in other countries be provided. In the interests of meeting public health objectives and as an integral step towards a substantive patent examination system the introduction of the requirement that the patent applicant disclose the best method of making the invention together with information relating to the status of patent applications for the same pharmaceutical

⁶¹⁶ See the recent ruling of the Canadian Supreme Court in the case of *Teva Canada Ltd. v. Pfizer Canada Inc.*, 2012 SCC 60, in which the Court, in paragraph 31 noted:

“The patent system is based on a “bargain”, or quid pro quo: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge. This is the basic policy rationale underlying the Act. The patent bargain encourages innovation and advances science and technology.”

compound in other countries could be an important step in South Africa, as would the requirement that the applicant disclose the international non-proprietary name (INN).⁶¹⁷

ii) Exhaustion of Rights, General Exceptions to Patent Rights

Article 6 of the TRIPS Agreement provides countries with the flexibility to determine what system of exhaustion of rights is applicable. Unlike most other countries, the exhaustion of rights has not been addressed in the Patents Act but in the Medicines and Related Substances Control Act.⁶¹⁸ The implications of including Section 15 (C) in the Act which authorizes parallel importation, have been discussed in Chapter three. Section 15 (C) is a broadly worded provision, the relevant portion of which notes that:

“The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (Act 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent”

The wording of Section 15 (C) has generated differences of opinion as to whether it can be read as authorizing compulsory licensing,⁶¹⁹ or whether it was drafted to facilitate parallel importation alone.⁶²⁰ The matter was never addressed by the Courts following the decision by the

⁶¹⁷ Park, Prabhala and Berger refer to a proposal by the Indian Pharmaceutical Alliance suggesting that disclosure of information on similar patent filings in other countries should include reference to the INN or the generic names assigned to pharmaceutical molecules as this would make it significantly easier to identify among a plethora of patent claims given the large volumes of patent filings with the US Patent and Trademark Office (PTO), the EPO, the Japanese Patent Office (JPO) and other large patent offices. In Uganda, civil society made a submission in 2012 for the disclosure of INNs by patent applicants. However, the Ugandan Industrial Property Act passed by Parliament in 2013 and signed by the President in 2014 does not contain the requirement to include INNs. The submission of the Centre for Health, Human Rights and Development, is [Online] Available: <http://www.cehurd.org/wp-content/uploads/downloads/2012/09/IP-Bill-model-provisions.pdf>

⁶¹⁸ Act 101 of 1965.

⁶¹⁹ See for instance Bombach K, ‘Can South Africa Fight Aids? Reconciling the South African Medicines And Related Substances Act with the Trips Agreement’, Boston University International Law Journal, 19, 273-306’

⁶²⁰ As noted in Abbott F, (2002) ‘WTO TRIPS Agreement and its Implications for Access to Medicines in Developing Countries’ Study Paper 2a, Commission on Intellectual Property Rights 53-54.

Pharmaceutical Manufacturers' Association to drop the Court case challenging the legality of Section 15(C).

On the issue of general exceptions to patent rights, the bolar exception found in Article 30 of the TRIPS Agreement has been incorporated into domestic legislation with the amendment of Section 69A(1) of the Patent Act thus making it permissible to work a patented product without the permission of the patent holder provided the purpose of the patent being worked is to obtain and submit information required to sell, distribute, market or produce a medicine in the country.⁶²¹ While it is commonly agreed that the incorporation of the bolar exception has the greatest bearing on the introduction of generic competition, the Act could be amended to include other general exceptions. The experimental use or scientific research exception in particular may be important for a country interested in promoting a pharmaceutical manufacturing industry in line with its industrial policy objectives. Many aspects of innovation entail making minor improvements to existing technologies. The ability of a country's scientific community to be able to make use of such technologies without fear of patent infringement can only serve to strengthen the likelihood that such innovation would occur.⁶²² Several developing countries including Brazil⁶²³ have adopted research exemptions for scientific purposes. While some authors note that countries have elected to specify under what grounds the research exceptions apply,⁶²⁴ it may be advantageous to the country's public health objectives to word the research exception as broadly as possible to include scientific research being undertaken by generic companies.

⁶²¹ Section 69A(1) reads as follows:

"It shall not be an act of infringement of a patent to make, use, exercise, offer to dispose of, dispose of or import the patented invention on a non-commercial scale and solely for the purposes reasonably related to the obtaining, development and submission of information required under any law that regulates the manufacture, production, distribution, use or sale of any product."

⁶²² Article 7 of the TRIPS Agreement notes that:

"The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare"

⁶²³ According to Brazil's Industrial Property Code of 1996, acts by third parties with an experimental purpose, specific to scientific or technological studies or research are permissible even if undertaken without the permission of the patent holder.

⁶²⁴ Some countries like Taiwan and Argentina allow the research exception only for non-commercial use, while others like Trinidad and Tobago or Turkey provide it for any experimental purposes.

5.3.4 Compulsory Licensing and Government Use

As discussed above in chapter three, compulsory licensing remains the most debated and attention generating public health related TRIPS flexibility. Compulsory licensing provisions may prove to be important for local producers who for now appear content to negotiate voluntary licenses with originator companies as a way of expanding their product portfolios. Aside from the potential benefit to generic manufacturing companies such as Aspen Pharmacare Adcock Ingram and Cipla-Medpro, the decision by the South African Government to develop a state-owned pharmaceutical industry to meet the public health needs of the population would be supported by the presence of compulsory licensing provisions which are expedient and relatively easy to use. The second reason relates more to treatment sustainability. When one considers that the South African Government invested approximately US\$1.8 billion in 2012 alone in its AIDS response⁶²⁵ and that most of the medicines used to treat people living with HIV through the South African public health care programme are generic, as more patients require new generation ARVs some of which remain expensive by South African standards,⁶²⁶ or as new treatments for TB, Hepatitis C and NCDs emerge, the need to promote generic competition through the use of compulsory licenses should increase. The presence of effective provisions which are simple to use must be a core component of a public health sensitive legislative framework.

Section 56 of the Patents Act regulates compulsory licensing and to some degree, incorporates some of the policy space provided by Article 31 of the TRIPS Agreement. However, a number of provisions impose additional conditions and requirements thus complicating their use. The first set of concerns with Section 56 are procedural in nature and start with Section 56(1) which reads:

“Any interested person who can show that the rights in a patent are being abused may apply to the commissioner in the prescribed manner for a compulsory licence under the patent.”

⁶²⁵ Ibid UNAIDS 2012.

⁶²⁶ According to the South Africa country website of the World Bank [Online] Available:

<http://data.worldbank.org/country/south-africa>

The Gross National Income (GNI) for South Africa in 2011 was approximately US \$ 6, 960 which does not factor in the fact that South Africa has among the highest levels of income inequality in the world.

By restricting authority to issue a compulsory license only to the patent commissioner, who is required by the Act to be a sitting or acting Judge,⁶²⁷ complete with formal judicial proceedings,⁶²⁸ the Act imposes the requirement for judicial proceedings to be undertaken before a compulsory license can be issued. The TRIPS Agreement merely requires that the decision to issue a compulsory license be subjected to a process of independent review, by a higher authority. This need not involve judicial proceedings⁶²⁹ and can involve the review by an administrative body distinct from the patent commissioner, duly appointed by a government official such as the minister of trade and industry, or even the minister him or herself.⁶³⁰ Litigation before the patent commissioner can take up to three years.⁶³¹ A ruling by the patent commissioner can also be appealed,⁶³² thus increasing the possibility of further delays should one of the parties tactically opt to delay the issuance of a compulsory license.

One way to prevent the possibility of a party resorting to litigation as a delay tactic would be to insert deadlines by which the process of a compulsory license application should take place. This can also be used to implement the requirement under Article 31(b) that the negotiations for a voluntary license must take place within a reasonable period of time. In addition to negotiations for voluntary licenses, timelines could be imposed for the hearing of a request for a compulsory license before the competent authority. Timelines can also be imposed to determine how quickly an appeal should be heard, and a final decision made. A further provision enabling the use, importation or production of a product that is the subject of a compulsory license in the situation of extreme urgency even before the conclusion of the appeal process could reduce the risk of a compulsory licensing being unduly delayed. Another option may be to increase the number of authorities who may grant a compulsory license beyond the patent commissioner. This could be done by explicitly conferring the right to issue a license to the Minister of Trade and Industry or an administrative body established by the Minister.

⁶²⁷ As required by Section 8 of the Act.

⁶²⁸ Section 19(1) requires all proceedings before the patent commissioner to be conducted in accordance with the High Court rules.

⁶²⁹ While judicial review is required to determine the remuneration rate set by the authority issuing the compulsory license, it need not delay the entry into market of the generic product, especially if the product, particularly if the product in question is an essential medicine.

⁶³⁰ See UNCTAD-ICTSD (2005) at 478.

⁶³¹ Ibid Park, Prabhala and Berger at 54.

⁶³² Section 76

There are a number of areas where the patents Act could be said to impede the ability of South African consumers to access affordable health technologies. One such instance relates to the grounds under which a compulsory license may be issued. Article 31 of the TRIPS Agreement does not limit the grounds under which a compulsory licence may be issued, a situation that was re-affirmed by the Doha Declaration on TRIPS and Public Health.⁶³³ By contrast, Section 56(2) limits the grounds under which a compulsory license may be issued to the following:

- (a) the patented invention is not being worked on a commercial scale or to an adequate extent, and there is, in the opinion of the patent commissioner, no satisfactory reason for such non-working;
- (b) the demand for the patented article is not being met to an adequate extent and on reasonable terms;
- (c) by reason of the refusal of the patentee to grant a licence or licences upon reasonable terms;
- (d) the establishment of any new trade or industry is being prejudiced;
- (e) it is in the public interest that a licence or licences should be granted; or
- (f) the demand in the Republic for the patented article is being met by importation and the price charged by the patentee, his licensee or agent for the patented article is excessive in relation to the price charged therefor in countries where the patented article is manufactured by or under licence from the patentee or his predecessor or successor in title.

While a case can be made that Section 56(2)(e) provides a sufficiently broad chapeau under which most claims can be brought in addition to the five other specific grounds, there are three glaring omissions in the Act. One of these is the absence of an expedient, clearly worded provision around the government use of a patented product without the patent holder's consent. A general provision on public non-commercial use of a patented invention can be found in Section 4 of the Patents Act, the relevant portion of which reads as follows:

⁶³³ Paragraph 5(b) of the Doha Declaration notes that:

"Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."

“... a Minister of State may use an invention for public purposes on such conditions as may be agreed upon with the patentee, or in default of agreement on such conditions as are determined by the commissioner on application by or on behalf of such Minister and after hearing the patentee.”

As noted above in Chapters three and four, the requirement under Article 31(b) of the TRIPS Agreement that prior negotiation must take place in order to obtain a voluntary license on reasonable terms and conditions and within a reasonable period of time is waived either in situations of national emergency, situations of extreme urgency or for public non-commercial use. Several countries have adopted wide-ranging government use provisions in which provide the state with the discretion to act as expeditiously as is required,⁶³⁴ something worth considering in the South African context as well.

Another important flexibility available under Articles 31(k) of the TRIPS Agreement is the possibility to issue compulsory licenses on the basis of anti-competitive behaviour. In such instances, the requirements under Article 31(b) are waived, as is the requirement in Article 31(f) that the license can only be used to predominantly supply the domestic market. This is an important flexibility in the South African context given the active involvement in the competition authority in previous matters on access to treatment.

Another omission in the current Act is the absence of a provision implementing the 30 August 2003 Decision. As noted above, the Decision allows for the wholesale export of health technologies produced under a compulsory license to be exported to other countries. This provision has added relevance in South Africa given its position both as a large producer of generic medicines and importer of essential health technologies. The latter may result in a potential revenue source for the government owned pharmaceutical industry if its plans to establish an API manufacturing are realised. The South African Government is well placed to use paragraph 6 of

⁶³⁴ For instance, Reichman J, (2006) ‘Compulsory Licensing of Patented Inventions: Comparing US Law and Practice with Options under the TRIPS Agreement’ presented at the AALS mid-Year Workshop on Vancouver, Canada notes that the US Code 1498 authorizes the government or its contractors to make any ‘*use or manufacture of a patented product or process “by or for the United States without license” and without incurring liability for infringement, other than a duty to pay “reasonable and entire compensation” to the patentee or his assignees for such use and manufacture.*’

the 30 August Decision which provides a waiver to Article 31(f) of the TRIPS Agreement for any regional economic organisations South Africa is a member of SADC, whose membership comprises at least 50 percent of LDCs. While the Government of South Africa is yet to ratify the 30 August Decision,⁶³⁵ it remains possible to use the Decision without having to ratify it. As discussed above in Chapter four, the Patent Act in Zanzibar was amended to incorporate the 30 August 2003 Decision although Tanzania is yet to ratify the amendment to Article 31 of the TRIPS Agreement.

The final substantive concern relates to the remuneration to be paid to a patent holder in the event a compulsory license is issued. While the TRIPS Agreement is silent on the issue, previous compulsory licenses issued for public health grounds as discussed in chapters three and four have limited the royalty rate to no more than 6 percent of the net cost of the licensed product. Zanzibar has explicitly included a provision which caps the royalty rate at 4 percent where a compulsory license is issued for anti-competitive behaviour and for the waiver of the royalty:

*“Where importation takes places pursuant to the Decision of the General Council of the WTO of August 30, 2003 or Article 31 bis of TRIPS whichever that is applicable, and the exporting country issues a compulsory licence for the same patented invention.”*⁶³⁶

The inclusion of language in the Patent Act or its enabling regulations providing guidance on the calculation of remuneration to be paid upon the issuance of a compulsory license may be necessary, but worth considering.⁶³⁷

⁶³⁵ As of October 2014, South Africa had not ratified the Decision according to a dedicated website maintained by the WTO Secretariat. The website is available at: http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm

⁶³⁶ Section 14(1)(b) of the Patent Act 4 of 2008.

⁶³⁷ Most countries that have recently issued compulsory licenses as a measure to increase access to essential medicines do not have provisions in their legislation providing guidance on the calculation of royalties, but rely on different methods to calculate royalties. In issuing a compulsory license in March 2012 for a cancer medicine in India, the patent controller was guided by the UNDP Royalty Guidelines recommending that a starting point of 4 percent royalty adjustable up or down depending on the therapeutic value of the medicine would be an appropriate fee. See page 60 of the compulsory licensing order of the Patent controller [Online] Available: http://ipindia.nic.in/ipoNew/compulsory_License_12032012.pdf.

The government of Indonesia for instance set a royalty rate of half a percent for compulsory licenses issued in 2004 and for seven compulsory licenses issued for the treatment of HIV and Hepatitis B in September 2012.

5.3.5 Provisions Relating to Intellectual Property Enforcement

As discussed in Chapter four, part III of the TRIPS Agreement contains the minimum requirements for WTO Members on intellectual property enforcement. Some of the key principles in the intellectual property enforcement provisions are first that they should not constitute a legitimate barrier to trade,⁶³⁸ second, decisions on the merits of a case shall be made expeditiously, and only on the basis of evidence which the parties were offered an opportunity to be heard and⁶³⁹ third, that any decisions made by administrative or judicial authorities on intellectual property enforcement should be subject to review.⁶⁴⁰ Unlike mainland Tanzania which has seen the introduction of new legislation on counterfeit medicines which may have negative implications on access to generic health technologies, South Africa's Counterfeit Goods Act⁶⁴¹ mostly avoids the controversial provisions found in east African counterfeiting legislation through the exclusion of patents from the scope of the Act.⁶⁴² That said, Section 2(1) criminalizes the sale, possession, exhibition, trade or distribution of counterfeit goods but does not impose the standard of "*wilful trademark counterfeiting on a commercial scale*" provided for under Article 61 of the TRIPS Agreement.

Article 44 of the TRIPS Agreement authorises judicial authorities to issue injunctions- or interdicts as they are referred to under South African law- preventing the entry into the market of goods that infringe the intellectual property. Article 44.2 does however provide an exception to the injunction rule, thus ensuring that medicines being imported under compulsory license are not subject to this provision.⁶⁴³

The Justice Harms of the South African Supreme Court of Appeal in commenting on interdicts has noted, that:

⁶³⁸ See Article 41.1.

⁶³⁹ See Article 41.3.

⁶⁴⁰ Article 41.4 reads:

"Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case."

⁶⁴¹ Act 30 of 1997.

⁶⁴² The definition of intellectual property under the Counterfeit Goods Act is limited to copyright and trademarks as is the case in the TRIPS Agreement.

⁶⁴³ This is subject to the payment of adequate remuneration, as envisaged by Article 31(h) of the TRIPS Agreement.

*“...final interdicts are granted as a matter of course in South Africa. Otherwise it would amount to granting the defendant a compulsory licence. It is nevertheless foreseeable that in, say, pharmaceutical patent cases, where public health concerns or the constitutional rights to health care arises, a court may have to consider whether or not to leave the rights holder to a damages claim instead of a final interdict”*⁶⁴⁴

With this in mind, Park, Prabhala and Berger recommend that the Act be amended in South Africa to include a specific provision that final interdicts shall not be granted where the payment of damages is sufficient adequately to compensate the patent holder or where it would not be in the public interest to do so.⁶⁴⁵

5.3.6 Competition related TRIPS Flexibilities

There are a number of reasons why competition law and policy present a good opportunity for developing countries to increase access to health technologies. First, it presents a fluid area of law under the TRIPS Agreement with no formal degree of consensus between WTO Members, the way for instance, the Doha Declaration on TRIPS and Public Health may have brought a degree of certainty regarding the ambits and limitations of patent law and policy. Second, developing countries retain significant more policy space and the freedom to interpret and implement the TRIPS Agreement under competition law. Moreover, the use of competition law as a public health related TRIPS flexibility is not dependent on political will.⁶⁴⁶ This is because unlike patent law, the initiation of competition complaints does not rely on the failure of certain parties such as ministries of trade and industry or health to take measures. As the use of competition law in South Africa has shown, action can be initiated by a range of parties including patient groups, generic companies, international relief organisations or interested parties that does not necessarily require such parties to invest significant resources.

⁶⁴⁴ Harms L, (2004) ‘The Role of the Judiciary in the Enforcement of Intellectual Property Rights: Intellectual Property Litigation Under the Common Law System With Special Emphasis on South Africa, prepared for the Second Session of the Advisory Committee on Enforcement, WIPO/ACE/2/4.

⁶⁴⁵ Ibid at 78-79.

⁶⁴⁶ Avafia T, Berger J, and Hartzenberg T, (2010) ‘Using competition law and policy to increase access to a sustainable supply of affordable medicines’ Paper 16, in “Intellectual Property and Access to Medicines: Papers and Perspectives” WHO SEARO, New Delhi, at 200 [Online] Available: <http://apps.who.int/medicinedocs/documents/s17521en/s17521en.pdf>

As noted in Chapter three, the South African Competition Act provides the most concrete example of how access to treatment objectives have been met by employing competition law and policy. The South African Act distinguishes itself from competition legislation of other countries whose primary focus is on preventing the monopolization of certain sectors of the economy, in that it explicitly provides for a broad range of economic and developmental goals as key among its aims and objectives.⁶⁴⁷ This is not uncommon in a number of LMICs where development objectives and the public interest are often listed as key drivers of competition legislation,⁶⁴⁸ but given the country's recent history, the emphasis on economic development is not surprising. According to Hartzenberg:

*“Competition challenges arose from South Africa’s apartheid history, its economic isolation, financial sanctions and high levels of market and ownership concentration, especially in mining and manufacturing.”*⁶⁴⁹

The aims and objectives of the Competition Act are consistent with Article 8 of the TRIPS Agreement which provides that WTO Members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of the TRIPS Agreement. The Act also establishes an independent investigatory body known as the Competition Commission,⁶⁵⁰ an adjudicatory body, the Competition Tribunal⁶⁵¹ and an Appeal body Competition Appeals Court,⁶⁵² to enforce the Act. Aside from its involvement in access to medicines and competition issues, the role played by the Competition Commission in the Hazel Tau complaint discussed in Chapter three, it is widely agreed that the South African

⁶⁴⁷ Section 2 on the purpose of the act includes among its objectives:

“ a) to promote the efficiency, adaptability and development of the economy;
b) to provide consumers with competitive prices and product choices;
c) to promote employment and advance the social and economic welfare of South Africans
e) to ensure that small and medium-sized enterprises have an equitable opportunity to participate in the economy;
f) to promote a greater spread of ownership, in particular to increase the ownership stakes of historically disadvantaged persons.”

⁶⁴⁸ Hartzenberg T, (2002) ‘Competition Policy in SADC, Trade and Industrial Policy Strategies (TIPS) 2002 Annual Forum) 1.

⁶⁴⁹ Ibid Hartzenberg at 8.

⁶⁵⁰ Section 19.

⁶⁵¹ Section 26.

⁶⁵² Section 36.

Competition Commission is a comparatively active institution with more than 2 800 intermediate mergers having been investigated, and 750 merger decisions having been given by the Tribunal between 1999 and 2011.⁶⁵³

The Competition Act contains a list of prohibited practices such as the abuse of dominance⁶⁵⁴ and within that, excessive pricing⁶⁵⁵ and refusing access to an essential facility⁶⁵⁶ in addition to a variety of specific exclusionary acts⁶⁵⁷ There are several other ways in which anti-competitive behaviour can manifest itself which go well beyond the scope of this chapter but insofar as provisions related to TRIPS flexibilities are concerned,⁶⁵⁸ one of the key remedies that should be included is compulsory licensing as envisaged by Article 31(k) of the TRIPS Agreement. Section 56 of the Patent Act could be expanded to include the possibility of a compulsory license being issued for anti-competitive behaviour and could be added as a remedy available to the competition tribunal⁶⁵⁹

It has also been previously noted elsewhere⁶⁶⁰ that the Competition Commission could choose to make use of its powers in Section 79(1) of the Competition Act to prepare guidelines which can be used to address the interface between intellectual property and anti-competitive behaviour. While these would not necessarily be binding, they would provide much needed guidance not only to policy makers but to consumers and the private sector. Finally, both the remedy of a compulsory

⁶⁵³ See Competition Commission South Africa Annual Report 2010/2011 [Online] Available: <http://www.compcom.co.za/assets/Publications/Annual-Reports/CC-Final-Annual-Report-2010-2011-lowres3.pdf> as discussed by Staples J, and Masamba M ,(2012) ‘Fourteen Years Later: An Assessment of the Realization of the Objectives of the competition Act 89 of 1998’, Siber Ink CC, Westlake, South Africa.

⁶⁵⁴ Section 8 of the Act.

⁶⁵⁵ Section 8(1).

⁶⁵⁶ Section 8(2).

⁶⁵⁷ Sections 8(3) and (4).

⁶⁵⁸ These include and are not limited to horizontal restraints such as price fixing, agreements limiting the geographical scope of sales, collusions and vertical restraints such as denying access to an essential facility, abusive of dominant position. For a thorough discussion of the various ways anti-competitive conduct may impede access to affordable treatment, see Abbott F, (2014) ‘anti-competitive behaviours and remedies available for redress’ in “Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries” Abbott F (ed), UNDP, New York, [Online] Available:

http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2439416

⁶⁵⁹ Under Part D of the Competition Act regulating tribunal hearings and orders.

⁶⁶⁰ Ibid Avafia, Berger and Hartzenberg 2010 at 200.

license and clear grounds for its issuance on the grounds of anti-competitive behaviour could be included in the Competition Act itself.⁶⁶¹

5.4 Conclusion

As discussed above, South Africa continues to shoulder a disproportionately high portion of the AIDS epidemic with the largest number of people living with HIV. The unprecedented public health crisis fuelled by the AIDS epidemic has galvanised the government into establishing the largest national HIV treatment programme in the world which, laudably, is mostly self-funded. The decision to domestically finance the bulk of its AIDS response would have contributed to the introduction of innovative cost reduction measures by the South African government linked to the national ARV tender.

While non-intellectual property related mechanisms have been successfully utilised to significantly reduce the cost of government sponsored ART, as patients start to make greater use of newer ARVs which, in some cases, will remain under patent protection for lengthy periods of time, the public health related TRIPS flexibilities will become of greater importance as senior Government officials have noted, which constitutes a validation of the first hypothesis advanced in chapter one. The release of the draft IP policy by the DTI in 2013 is an important sign that the government is starting to prioritize legislative reform in order to keep treatment costs sustainable in the long term and an additional validation of the first hypothesis. The need to identify a long term sustainable source of ART is also one of the underlying factors behind the increased focus on local pharmaceutical production as an industrial policy objective and the decision by the government to establish a government owned pharmaceutical manufacturing entity with the capacity to produce APIs.

Given its comparative sophistication and economic size, it is clear that South Africa possesses more related capacity both within its government and civil society sectors than any other country in the region to incorporate and use public health related TRIPS flexibilities. Civil society has been

⁶⁶¹ Ibid at 200-201 for more recommendations regarding possible amendments to the Competition Act to remedy anti-competitive behaviour.

particularly active in using both the Bill of Rights and national legislation to facilitate treatment access. The South African legislative framework is also the most complex in the region with public health related TRIPS flexibilities present in medicines, patent and competition legislation. However, for all the progress the South African Government has made in the past decade aimed at making treatment sustainable, it lags behind on policy and legislative reform. While there is room for further flexibilities to be incorporated into legislation such as a clearer provision around patentability criteria and some general exceptions under Article 30 of the TRIPS Agreement, and for the refinement of existing flexibilities such as compulsory licensing for private and public non-commercial use, the most important policy change under the TRIPS Agreement must be the decision to start examining pharmaceutical patents in order to reduce the number of incremental innovations that are automatically granted patents, and to ensure that only patents of the highest quality are granted.

However, the fact that the Department of Trade and Industry has to date, relied on a system of patent registration rather than substantive examination means that it faces a critical shortage of qualified patent examiners to implement a change from registration to examination. This capacity constraint supports the hypothesis advanced in chapter two that capacity constraints in government departments in eastern and southern African countries could hinder the integration and effective use of public health related TRIPS flexibilities.

As examined above, South Africa possesses a complex but rich legislative framework spanning across industrial property, medicines, and competition legislation that can be leveraged in order to increase access to treatment. While there are advantages to employing various pieces of legislation to promote competition or to generally decrease the cost of treatment, a consequence of South Africa's legislative framework is that there are several ministries involved in administering and implementing relevant legislation.

At present, the Department of Trade and Industry is responsible for administering the Patents Act while the Department of Health is responsible for the administration of the Medicines and Related Substances Control Act and the Department of Economic Development oversees the Competition Act. On the other hand, implementation of the government's plans to develop a local

pharmaceutical industry is led by the Department of Science and Technology with the participation of the Departments of Trade and Industry, Health, Economic Development, Energy and the Treasury. The degree to which these actors are working towards the governments common objectives of promoting local pharmaceutical production and sustaining large self-financed treatment programmes is questionable given the recent establishment of Pan African Intellectual Property Office (PAIPO) through the African Union.⁶⁶² As will be discussed below in chapter six, a major proponent of PAIPO was the South African Department of Science and Technology which has been involved in inter-departmental discussions around the establishment of a state owned pharmaceutical company but otherwise is not involved in formulation, writing or implementation of any of the key pieces of legislation in where TRIPS flexibilities are present.

The involvement of a ministry in the establishment of a regional organisation whose impact on the government's treatment sustainability and local pharmaceutical production objectives is unclear which supports the third hypothesis advanced in chapter one regarding the policy incoherence between national stakeholders and the potentially harmful impact this could have on the sustainability of national treatment programmes. Another sign that the various government stakeholders are not necessarily aligned was the notable absence of any official from the Department of Health from a forum organised by the Department of Trade and Industry in February 2013 to discuss the role of intellectual property in facilitating treatment access in Africa.⁶⁶³

⁶⁶² Following a decision in 2007 by African Heads of State and Government of the African Union to establish PAIPO, African Ministries of Science and Technology have been leading efforts to establish a single African intellectual property agency. The AU Scientific, Technical and Research Commission started drafting the statutes of this new entity with a validation exercise taking place at a stakeholder's Workshop in 2011, in Senegal. The final draft of the PAIPO statute was submitted to AU Member States and at a meeting in January 2013, a decision was reached to establish PAIPO. In April 2014, a communiqué was adopted by the joint meeting of the chairmen of ARIPO and OAPI in Harare, Zimbabwe which mentioned the fact that ministers involved in the administration of intellectual property matters noting that they had not been consulted in African Ministerial Conference on Science and Technology (AMCOST) meetings which led to the establishment of PAIPO, and requesting that an urgent stakeholder's meeting be convened to enable the participation of all stakeholders including ARIPO, OAPI and WIPO and that the national ministries responsible for the administration of intellectual property play a key role in the establishment of PAIPO.

⁶⁶³ Information on the Forum can be found on the website of the DTI [Online] Available: http://www.dti.gov.za/business_regulation/business_regulation.jsp

A government official noted that the absence was a manifestation of the policy tensions which existed between the Department of Trade and Industry on the one hand, and the Department of Health on the other, over the regulation of intellectual property.

6 South-South Co-operation: Opportunities and Challenges for Eastern and Southern African Countries Within the Region and Beyond

“Cross the river in a crowd and the crocodile won’t eat you.”

African proverb

The past few years have seen an unprecedented level of activity by countries in eastern and southern Africa in promoting intra-regional co-operation on access to health technologies. In assessing the potential public health impact of efforts to date, this chapter examines the ways in which bilateral and sub-regional co-operation between countries with differing degrees of pharmaceutical production capacity in eastern and southern Africa could facilitate a sustainable supply of health technologies. In so doing, this chapter will examine the various sub-regional and continental initiatives embarked upon in recent years and test the first hypothesis advanced in chapter one, namely that public health related TRIPS flexibilities will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs. In testing the second hypothesis namely, advanced in chapter one, namely that capacity constraints have impeded the incorporation and use of public health related TRIPS flexibilities, this chapter investigates some of the capacity constraints facing countries in the region which have may have led to their involvement in regional initiatives and mechanisms that appear in some instances to prioritize intellectual property protection and enforcement above access to affordable health.

To test the third hypothesis advanced in chapter one, namely that a significant degree of policy incoherence in the form of national legislation and regional initiatives could undermine the incorporation and use of public health related TRIPS flexibilities in the national and regional level, this chapter examines how also examines how policy incoherence has impeded existing initiatives aimed at expanding treatment. This chapter also discusses how the reform of enabling statutes and examination policies at ARIPO could improve the ability of countries to promote sustainable national treatment programmes. The chapter also explores ways that increased co-ordination can

increase opportunities for regional co-operation in the EAC,⁶⁶⁴SADC⁶⁶⁵ and to a lesser degree, COMESA⁶⁶⁶ thus facilitating more favourable public health outcomes in the region and at multilateral forums where normative intellectual property related rules are developed. Finally, this chapter draws on how intellectual property legislation and policy reform can be used to facilitate south-south co-operation in the region.

6.1 Opportunities for sub-regional co-operation in the East African Community

The EAC was officially established on 30 November 1999 with the signing of a treaty by the original three Partner States – Kenya, Tanzania and Uganda.⁶⁶⁷ The Republic of Rwanda and the Republic of Burundi acceded to the EAC Treaty on 18 June 2007⁶⁶⁸ thus bringing the membership to its current number of five. The EAC aims to deepen the integration process among the five Partner States, thus resulting in the establishment of a customs union,⁶⁶⁹ the adoption of a Common Market Protocol and plans to adopt a Monetary Union Protocol.⁶⁷⁰ The EAC Customs Union requires Partner States to conclude protocols in the cooperation in intellectual property rights, which shall spell out the objectives, scope of co-operation and institutional mechanisms for co-operation.⁶⁷¹

⁶⁶⁴ Given Tanzania's membership of the EAC.

⁶⁶⁵ South Africa and Tanzania are two of the 15 Member States of SADC.

⁶⁶⁶ While Tanzania withdrew from COMESA in 1999, all the remaining Partner States of the EAC- Burundi, Kenya, Rwanda and Uganda- are still Member States of COMESA. Furthermore, several SADC Members also continue to be Members of COMESA, including the Democratic Republic of the Congo, Madagascar, Malawi, Mauritius, Seychelles, Swaziland, Zambia and Zimbabwe.

⁶⁶⁷ The treaty came into force on 7 July 2000 upon ratification Kenya, Tanzania and Uganda.

⁶⁶⁸ Burundi and Rwanda became full Members of the Community with effect from 1 July 2007.

⁶⁶⁹ As ratified by Kenya, Tanzania and Uganda in 2004 and subsequently by Burundi and Rwanda in 2008. The customs union is being implemented incrementally with the eventual goal of an integrated trading bloc in mind.

⁶⁷⁰ In November 2007, the EAC heads of state directed the EAC Secretariat to develop a strategic framework to fast-track the achievement of the monetary union. Negotiations to conclude a Monetary Union Protocol commenced in January 2011. See EAC Secretariat "East African Community Facts and Figures 2012" Arusha, Tanzania [Online] Available: http://www.eac.int/statistics/index.php?option=com_docman&Itemid=153

In July 2013, agreement was reached on a draft protocol which will lead to the integration of the Members financial markets over a 10 year period subject to the meeting of milestone targets by individual members.

⁶⁷¹ Articles 38.1(d) and 38.2 of the Protocol on the Establishment of the East African Community.

The map displays the following details:

- Countries:** Sudan, Ethiopia, Kenya, Uganda, Rwanda, Burundi, Tanzania.
- Major Cities:** Kampala (Uganda), Nairobi (Kenya), Kisumu (Kenya), Kigali (Rwanda), Bujumbura (Burundi), Kampala (Uganda), Dodoma (Tanzania), Mombasa (Kenya), Malindi (Kenya), Tanga (Kenya), Zanzibar (Tanzania).
- Geographical Features:**
 - Lakes:** Lake Albert, Lake Edward, Lake Kivu, Lake Tanganyika, Lake Victoria, Lake Turkana.
 - Mountains:** Mt. Elgon (14,173 ft.), Mt. Kenya (17,058 ft.), Mt. Kilimanjaro (19,340 ft.).
 - Deserts/Plains:** Chalbi Desert, Serengeti Plain, Lotikipi Plain, Masai Steppe.
 - Valleys:** Great Rift Valley.
- Other Labels:** Mandera, Garissa, Pwani, Pemba I., Zanzibar I., Bukavu, Kabale, Masaka, Jinja, Vushuni, Gulu, Arusha, Tabora, Kigoma, Uvira, Lake Albert, Lake Edward, Lake Kivu, Lake Tanganyika, Lake Victoria, Lake Turkana, Chalbi Desert, Lotikipi Plain, Masai Steppe, Serengeti Plain, Mt. Elgon, Mt. Kenya, Mt. Kilimanjaro, Mandera, Garissa, Malindi, Tanga, Zanzibar, Zanzibar I., Pemba I., Dodoma, Kampala, Nairobi, Kisumu, Kigali, Bujumbura, Kampala, Jinja, Masaka, Vushuni, Gulu, Arusha, Tabora, Kigoma, Uvira, Lake Albert, Lake Edward, Lake Kivu, Lake Tanganyika, Lake Victoria, Lake Turkana.

The Treaty establishing the EAC notes that its Partner States may work together to promote public health goals.⁶⁷² In line with the Treaty, an area identified early in the regional integration process was that of intra-regional co-operation to increase access to treatment for HIV and its co-infections. The growing expectation that countries in eastern and southern Africa should assume greater domestic responsibility for treatment programmes⁶⁷³ coupled with a rapid scale up in HIV treatment has prompted countries in the EAC to more rigorously explore industrial and regulatory options to make treatment programmes sustainable. Two of them: the EAC Regional Pharmaceutical Manufacturing Plan of Action and the EAC TRIPS Protocol are discussed below in more detail.

⁶⁷³ Moszynski P, (2010) 'Donor fatigue is slashing access to AIDS care in Africa, warns charity' *BMJ*; 340:c2844.

6.1.1 EAC Regional Pharmaceutical Manufacturing plan of Action

The EAC Partner States developed a Regional Pharmaceutical Manufacturing Plan of Action (EAC-RPMPoA) from 2012-2016 for a number of reasons.⁶⁷⁴ First, they were mindful of the large number of EAC citizens living with HIV, TB, malaria and other diseases who would be in need of sustainable treatment options, which, it was increasingly felt, required an investment in local pharmaceutical production.

Table 4: Anticipated need for medicines to treat HIV, TB and Malaria in the EAC

Cases/need/demand	Malaria		Tuberculosis		HIV/AIDS	
	2007	2018	2007	2018	2007	2018
Number of cases (000s)	141,050	191,463	437	603	3,990	5,338
Total need (USD, 000s)	185,541	309,224	3,516	4,847	218,494	488,893
Effective demand (USD, 000s)	4,391	59,997	1,640	2,805	56,251	131,157

Source: East African Community Regional Pharmaceutical manufacturing Plan of Action

Second, they were driven by a commitment to make as much progress as possible towards attaining as many of the health related Millennium Development Goals (MDGs) as possible by the 2015 deadline. Third, they were conscious of the shift in policy space available to countries with significant pharmaceutical manufacturing capacity, most notably, India's implementation of the TRIPS Agreement as of 1 January 2005. Finally, the then looming deadline of 1 January 2016, by which time, the exemption granted to LDCs under the Doha Declaration⁶⁷⁵ created a sense of urgency. The objective of the RPMPoA is to develop an efficient and effective pharmaceutical manufacturing industry that could one day supply national, regional and international markets with

⁶⁷⁴ See *The EAC Regional Pharmaceutical Manufacturing Plan of Action 2012-2016*, East African Community Secretariat, Arusha at 13 [Online] Available: http://feapm.com/fileadmin/user_upload/documents/EAC_Regional_Pharmaceutical_Manufacturing_Plan_of_Action.pdf

⁶⁷⁵ Paragraph 7 of the Doha Declaration.

medicines required to treat both communicable and non-communicable diseases⁶⁷⁶ through the promotion of competitive and efficient regional pharmaceutical production, the strengthening of pharmaceutical regulatory capacity in the region and increased use of public health related TRIPS flexibilities towards improved local production of pharmaceuticals.⁶⁷⁷

With the overall aim of improving local production prospects, the intellectual property related objectives of the RPMPoA are:

- (i) National and regional sensitization on intellectual property rights and public health related WTO-TRIPS flexibilities;
- (ii) Adoption of a regional policy framework and guidelines to effectively implement public health related TRIPS flexibilities; and
- (iii) Domestication of public health related TRIPS flexibilities within national laws.

The eventual success of intra-regional co-operation on local pharmaceutical production depends on the optimal use of policy space available under the TRIPS Agreement by each Partner State of the EAC. The second hypothesis postulated in chapter one of this thesis, namely, that there are capacity constraints within the relevant government departments in the region that hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation is supported by the numerous national and regional capacity strengthening events being organised by bilateral and multilateral organisations with a focus on intellectual property and treatment access.⁶⁷⁸ These capacity strengthening activities have been on-going for a number of years within the EAC.⁶⁷⁹ In the case of Zanzibar these activities led to the adoption of a new Industrial Property

⁶⁷⁶ Ibid EAC at 30.

⁶⁷⁷ Ibid EAC at 30. The full lists of objectives are discussed in more detail between pages 30-32.

⁶⁷⁸ These include events organized by The South Centre, TWN, UNDP, WHO, UNIDO, UNCTAD, GIZ, WTO and WIPO.

⁶⁷⁹ For example, in 2005, UNDP held a training workshop in Arusha for Partner States of the EAC on public health related TRIPS flexibilities. Since then, national workshops for trade and health officials have been held for mainland Tanzania in 2005 by the WHO and then in 2006 by UNDP in partnership with TWN and WHO. Another national workshop was held in Zanzibar in 2007 by UNDP focusing on inserting more public health sensitive provisions into a draft Act prepared by WIPO. Two national workshops were also organised by UNDP in Uganda in 2011. Numerous national and regional workshops have also been held in various EAC Partner States by GIZ, UNCTAD, and UNIDO since 2006. The US PTO has undertaken trainings focused on intellectual property enforcement. Several workshops have also been held by WIPO on a broad range of intellectual property matters, some of which are listed on the WIPO website [Online] Available:

http://www.wipo.int/meetings/en/archive_meeting.jsp?meeting_country=176..

Act in 2008,⁶⁸⁰ and in the case of both Burundi,⁶⁸¹ and Rwanda,⁶⁸² to the adoption of new intellectual property laws in 2009. Neither Kenya⁶⁸³ nor mainland Tanzania,⁶⁸⁴ have undertaken significant amendments to their patent legislation with implications for treatment access in the past decade though a draft Act was prepared for Mainland Tanzania by WIPO, which is also assisting with the finalisation of a policy as discussed in chapter four.

6.1.2 The EAC Regional Policy on Intellectual Property and TRIPS Protocol

Aside from provisions present in the Customs Union Protocol, the Treaty establishing the EAC notes that Partner States agreed to undertake to promote intra-regional co-operation in the field of science and technology through the harmonisation of policies on the promotion and protection of intellectual property rights and to undertake such additional activities in that regard as the Council may determine.⁶⁸⁵ Intra-regional co-operation on public health related intellectual property has taken two forms: a regional intellectual property policy on using public health related TRIPS flexibilities⁶⁸⁶ and an EAC regional Protocol on public health related TRIPS flexibilities both of which are discussed below.

The genesis of the EAC regional policy dates back to 2005, when the Secretariat launched an initiative to harmonise policies, legislation and regulations on intellectual property in order to facilitate intra-regional trade and local pharmaceutical production of essential medicines. The EAC Secretariat with the support of GIZ finalised the policy in February 2013. Designed as a ‘roadmap’ to EAC Partners on what type of law reform is required of each country to optimise policy space available in the TRIPS Agreement, the policy makes several key recommendations for each Partner State regarding the integration of public related TRIPS flexibilities into national

⁶⁸⁰ Ibid chapter four.

⁶⁸¹ Intellectual property law 1/13 of 2009.

⁶⁸² Law 31 of 2009 on the Protection of Intellectual Property.

⁶⁸³ Industrial property Act of 2001.

⁶⁸⁴ The Patents Registration Act of 1995.

⁶⁸⁵ See Articles 103.1 (i) and 103.2 of the Treaty establishing the EAC.

⁶⁸⁶ the EAC Regional Intellectual Property Policy on the Utilisation of Public Health Related WTO-TRIPS Flexibilities and the Approximation of National Intellectual Property Legislation [Online] Available: <http://www.cehurd.org/wp-content/uploads/downloads/2013/05/EAC-TRIPS-Policy.pdf>

legislation. A brief summary⁶⁸⁷ of the recommendations in the policy in relation to various public health related TRIPS flexibilities can be found in Appendix two.

The recommendations in the EAC regional policy on intellectual property have been replicated in a draft Regional Protocol on public health related TRIPS flexibilities.⁶⁸⁸ The value added of having directives on intellectual property addressed in the Protocol is that it provides clear political guidance to the Partner States about the common objectives, and interpretive value where needed. However, unlike a treaty,⁶⁸⁹ the Protocol does not create a legal obligation on the Partner States to enact legislation giving effect to its contents.

As discussed above in Chapter two, the EAC has in recent years, seen the emergence of anti-counterfeiting legislation, both at the national⁶⁹⁰ and the regional levels with the draft EAC anti-counterfeiting policy and Bill.⁶⁹¹ In the case of the EAC, the draft Bill contains a problematic definition of anti-counterfeiting⁶⁹² which neither captures the definition provided by the WHO⁶⁹³ which makes it clear that counterfeiting can affect both originator and generic medicines, nor the

⁶⁸⁷ The full list of recommendations on these flexibilities and others including exclusions from patentability, patent oppositions and disclosure requirements as well as some recommendations related to ARIPO are found on pages 13-21 of the policy.

⁶⁸⁸ Draft East African Community Regional Protocol on Public Health Related WTO-TRIPS Flexibilities (2010), on file with author.

⁶⁸⁹ According to Article 8.4 of the Treaty establishing the EAC:

“Community organs, institutions and laws shall take precedence over similar national ones on matters pertaining to the implementation of this Treaty.”

⁶⁹⁰ As discussed above in Chapter two, Kenya and Tanzania passed anti-counterfeiting legislation and regulations in 2008, while in 2009 a draft counterfeit Goods Bill was developed in Uganda, which has as yet, not been passed.

⁶⁹¹ At the regional level, the EAC Secretariat commenced work to draft anti-counterfeiting policy in 2008, culminating in the emergence of a draft anti-counterfeiting Bill in early 2010 and the finalization of the draft Policy on ‘Anti-counterfeiting, anti-piracy and other intellectual property rights violations.

⁶⁹² The Bill describes a counterfeit as:

“...the possessing, manufacturing, producing or making, packaging, repackaging or labelling whether in the Community or elsewhere, of any goods whereby those protected goods are imitated in such manner and to such a degree that those other goods are substantially identical copies of the protected goods without the authority of the Owner of any Intellectual Property Right subsisting in the relevant Partner State in respect of Protected Goods;(or) the possessing, manufacturing, producing or making or applying to goods, whether in the Community or elsewhere, the subject matter of that Intellectual Property Right, or a colourable imitation thereof so that the other goods are calculated to be confused with or to be taken as being the Protected Goods of the said Owner or any goods manufactured, produced or made under his license without the authority of the Owner of any Intellectual Property Right subsisting in the relevant Partner State in respect of the Protected Goods.”

⁶⁹³ According to the 1992 definition of the WHO:

“A counterfeit medicine is one which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients, wrong ingredients, without active ingredients, with insufficient quantity of active ingredient or with fake packaging.”

TRIPS Agreement⁶⁹⁴ which limits its definition of counterfeit to trademarks. Beyond issues of definition, there are also public health implications around several other provisions in the draft EAC anti-counterfeiting Bill including criminal liability, rules around the seizure and storage of suspected counterfeit goods, rules of evidence during hearings over suspected counterfeit goods, as well as goods in transit and liability over the loss or damage of goods. It is not clear when the draft EAC anti-counterfeiting policy and Bill will be finalised, but it remains important that the flexibilities so carefully articulated in the regional intellectual property Policy and Protocol are not diluted by an over-reaching if well intentioned anti-counterfeiting policy and legislation.

In conclusion, the EAC's relatively small membership, coupled with its recent history of co-operation on intellectual property and local pharmaceutical manufacturing matters has increased the likelihood of successful intra-regional co-operation to promote access to treatment. Four of the six territories in the Community: Burundi, Rwanda, Uganda and Zanzibar, have recently amended industrial property and patent legislation and have mostly incorporated public health related TRIPS flexibilities required to facilitate treatment access although additional policy space remains unused. As discussed above in chapter four, law reform planned for mainland Tanzania as well. However, as discussed overly broad draft anti-counterfeiting legislation could unnecessarily complicate the opportunities for effective regional co-operation.

6.2 Opportunities for sub-regional co-operation in the Southern African Development Community

The Republic of South Africa and the United Republic of Tanzania are now also both Member States of SADC, a regional economic community formed in 1980 initially as an alliance of nine

⁶⁹⁴ Article 51 of the TRIPS Agreement limits its definition of counterfeit to trademarks and notes:

“counterfeit trademark goods” shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation.”

countries aiming to reduce reliance on then apartheid South Africa.⁶⁹⁵ SADC has a current membership of 15 States.⁶⁹⁶

Figure 7: Member States of SADC



Source: SADC Secretariat

SADC co-operates on a wide range of development related issues with 22 protocols having been concluded and signed including protocols on trade, health and legal affairs. In response to the high burdens of disease in the region, SADC has been compelled to prioritize the development of a plan to scale up and maintain treatment programmes for HIV and TB, with an eye on increasing levels of NCD burdens in the region. A SADC Protocol on health has been in force since 2004.⁶⁹⁷ Article 10 of the SADC Health Protocol calls on countries to co-operate in harmonizing, and where appropriate, standardising policies in a number of areas, including on the treatment and management of communicable diseases. Shortly after the entry into force of the Protocol the SADC pharmaceutical Programme was established in 2005 to enhance the capacities of Member States to effectively prevent and treat diseases that are of major concern to public health in the region by

⁶⁹⁵ As discussed in more detail in ‘Southern Africa: toward Economic Liberation; a declaration by the governments of independent states of Southern Africa made at Lusaka on the 1st April 1980.’

⁶⁹⁶ Angola, Botswana, Democratic Republic of the Congo, Lesotho, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, Swaziland, Tanzania, Zambia and Zimbabwe.

⁶⁹⁷ The SADC Health Protocol was developed in 1999 and entered into force in 2004 upon reaching a threshold of ratifications required.

addressing matters concerning access to quality medicines. It aims to improve the availability of affordable; safe; efficacious; and effective essential medicines of acceptable standard.⁶⁹⁸ The most significant amount of intra-regional co-operation on intellectual property and access to medicines in SADC has taken place under the SADC Pharmaceutical Business plan.

6.2.1 The SADC Pharmaceutical Business Plan: Implications for Member States

Developed in 2007, the main aim of the SADC Pharmaceutical Business Plan is to improve sustainable availability and access to affordable, quality, safe, efficacious essential medicines.⁶⁹⁹ The modalities for doing so include harmonizing essential medicines lists and treatment guidelines in the region, developing local pharmaceutical production capacity, strengthening the capacity of drug regulatory authorities in the region to control the marketing, sale and distribution of medicines, promoting the joint procurement of medicines by SADC Member States to harness efficiencies generated by economies of scale and to co-ordinate the implementation of TRIPS flexibilities to increase access to treatment.⁷⁰⁰ The Pharmaceutical Business Plan has benefitted from the involvement of donors who have established the Southern African Regional Programme on Access to Medicines and Diagnostics (SARPAM) to support the implementation of the Business Plan.⁷⁰¹

Several of the strategies outlined in the Business Plan whether they relate to increasing local pharmaceutical production levels in the region, or the importation of either patented⁷⁰² or generic medicines⁷⁰³ may rely on the ability of SADC Member States to use public health related TRIPS

⁶⁹⁸ See the According to the SADC Pharmaceutical Business plan of 2007-2013, page 8 [Online] Available: http://www.unido.org/fileadmin/user_media/Services/PSD/BEP/SADC%20PHARMACEUTICAL%20BUSINESS%20PLAN%20-APPROVED%20PLAN.pdf

⁶⁹⁹ Ibid SADC Pharmaceutical Business Plan at 14.

⁷⁰⁰ See pages 13-17 of the Pharmaceutical Business plan for more information.

⁷⁰¹ Funded by the UK Department for International Development, (DFID) SARPAM was established in October 2011 and is operational until December 2014. Its purpose is to promote a more efficient and competitive market for essential medicines in the Southern African region to meet the health needs of poor people. More information on SARPAM is available [Online] at: <http://www.sarpam.net/about-sarpam-2/about-sarpam>

⁷⁰² Through parallel importation.

⁷⁰³ This may either be the importation of generic medicines through a compulsory license to one country in the SADC region. It could also be through the use of the 30 August 2003 Mechanism. At present, more than half of SADC's 15 Members, namely, Angola, the Democratic Republic of the Congo, Lesotho, Madagascar, Malawi, Mozambique, Tanzania and Zambia are classified as LDCs.

flexibilities. Since the start of 2013, SARPAM has been strengthening the capacity of countries on incorporating public health related TRIPS flexibilities, in partnership with UNDP.⁷⁰⁴ As is the case with the EAC, several multilateral and civil society organisations have engaged in capacity development activities around intellectual property and access to essential medicines for SADC Member States.⁷⁰⁵ The involvement of several organisations in activities to strengthen the capacity of various officials on intellectual property issues is an indication of the lack of sufficient capacity in the region on these issues. It is often also an enabler of policy incoherence given the different advice provided to countries in the region by various organisations.

As discussed above in chapter three, countries in eastern and southern Africa have a mixed record of success in employing public health related TRIPS flexibilities to increase access to treatment. This mixed record of success applies to the SADC region too. Zimbabwe's government use order in 2003 resulted in a price reduction in a commonly used ARV, while two compulsory licenses issued by Zambia and Mozambique for local production of a widely used combination ARV did not result in the production of the medicines.

Unlike the EAC however with its relatively small membership of five Partner States, and long history of regional and economic integration, SADC has a far larger membership of 15 countries and has only recently prioritized economic co-operation and regional integration after years of advancing a common political agenda. SADC also has three official languages,⁷⁰⁶ and large disparities in economic development between its Members.⁷⁰⁷ While there has been an increase in law and policy reform to facilitate regional co-operation in order to increase access treatment,

⁷⁰⁴ As of October 2014, national meetings had been held in Zambia, Malawi, Lesotho, the Seychelles, Botswana, and Zimbabwe with plans to undertake additional trainings in Swaziland before the end of 2014. See SARPAM [Online] Available: <http://www.sarpam.net/about-sarpam-2/pacts/tatm-trade-trips-and-access-to-medicines>

⁷⁰⁵ These include SARPAM, The South Centre, Third World Network, UNAIDS, UNCTAD, UNDP, WIPO, WHO the WTO as well as the USPTO.

⁷⁰⁶ English, French and Portuguese.

⁷⁰⁷ According to the IMF, between 2005 and 2009, South Africa alone accounted for approximately 65 percent of SADC's nominal GDP. Eight countries accounted for less than 10 percent of the nominal GDP. Seychelles and Mauritius are listed in 46th and 80th place respectively out of 187 countries ranked by the UNDP's Human Development Index (HDI) of 2012, while Malawi, Zimbabwe Mozambique and Democratic Republic of the Congo are ranked in 170th, 172nd, 185th and last place respectively.

since the SADC Pharmaceutical Business Plan was adopted in 2007, only Namibia⁷⁰⁸ Zanzibar,⁷⁰⁹ Botswana⁷¹⁰ and most recently, Seychelles⁷¹¹ have amended their laws to incorporate more public health related TRIPS flexibilities. A number of countries in the region are in the process of amending their intellectual property legislation, which presents an opportunity to incorporate more public health related TRIPS flexibilities as envisaged by the Pharmaceutical Business Plan. As discussed above, South Africa is amending its intellectual property legislation,⁷¹² as is Zambia,⁷¹³ Lesotho,⁷¹⁴ Swaziland,⁷¹⁵ Malawi,⁷¹⁶ and mainland Tanzania.⁷¹⁷

Despite the flurry of activity in some SADC Member States regarding to patent law reform, there is no indication from a number of countries in the region including that Angola,⁷¹⁸ DRC,⁷¹⁹ Madagascar,⁷²⁰ Mauritius,⁷²¹ Mozambique,⁷²² or Zimbabwe⁷²³ are planning any intellectual property reform that would further integrate public health related TRIPS flexibilities into their domestic legislation. There are also large disparities between countries regarding the extent to which public health related TRIPS flexibilities required to facilitate regional co-operation have been incorporated. For example, of the 16 patent and industrial property laws currently in force in

⁷⁰⁸ With the passing of the Industrial Property Act 1 of 2012 [Online] Available:

<http://www.lac.org.na/laws/2012/4907.pdf>

⁷⁰⁹ Industrial Property Act 4 of 2008.

⁷¹⁰ Industrial Property Act of 2010 [Online] Available: <http://www.wipo.int/wipolex/en/details.jsp?id=9602>

⁷¹¹ As of October 2014, Seychelles was in the final stages of WTO accession and to this end, passed the Industrial Property Act 7 of 2014.

⁷¹² With the release of the draft IP Policy by the DTI as discussed above in chapter five.

⁷¹³ A draft Patent Bill was developed for Zambia in 2011. According to a patent examiner with the Patents and Companies Registration Agency (PACRA), the new Patent Bill contains several public health related TRIPS flexibilities and has been introduced to Parliament. See a presentation made by Chilambwe at a WIPO seminar entitled '*Regional Seminar for Certain African Countries on the Implementation and Use of Several Patent-Related Flexibilities*' in Durban, South Africa, in January 2013 [Online] Available:

http://www.wipo.int/edocs/mdocs/patent_policy/en/wipo_ip_dur_13/wipo_ip_dur_13_ref_t7c.pdf

⁷¹⁴ Intellectual Property Order 5 of 1989 as amended in 1997.

⁷¹⁵ Swaziland is in the process of replacing its Patents, Utility Models and Industrial Designs Act No. 6 of 1997 with a draft Patents Bill developed in 2012 which is yet to enter into force. SARPAM and UNDP are providing technical support to integrate public health related TRIPS flexibilities.

⁷¹⁶ Malawi is the process of adopting its first Intellectual Property Policy. The Malawi Law Commission has also embarked on the process of revising the 1957 Patents Act according to SARPAM.

⁷¹⁷ As early as in 2006, WIPO Provided Mainland Tanzania with a copy of a WIPO model industrial property law, on file with author.

⁷¹⁸ Industrial Property Law No 3/92.

⁷¹⁹ Law No. 82-01 of 1982.

⁷²⁰ Ordonnance No. 89-019 instituant un régime pour la protection de la propriété industrielle en République démocratique de Madagascar de Juillet 1989.

⁷²¹ The patents, Industrial Designs, and Trademark Act No. 25 of 2002

⁷²² Industrial Property Code: Decree No. 4/2006.

⁷²³ Patents Amendment Act, 1978, as amended in 2002 and 2005.

SADC⁷²⁴ only four, namely Botswana,⁷²⁵ Namibia,⁷²⁶ South Africa,⁷²⁷ and Zanzibar⁷²⁸ contain bolar exception provisions. Even where countries have universally adopted certain public health related TRIPS flexibilities such as compulsory licensing, the substantive grounds under which a license can be issued and the procedural processes vary greatly.⁷²⁹

In addition to patent and industrial property legislation, there may be opportunities to insert public health related TRIPS flexibilities into the competition legislation of several SADC Member States. These include provisions to regulate the more traditional examples of anti-competitive behaviour such as abuse of dominance,⁷³⁰ or excessive pricing. These could also include specific remedies for measures where abuse of intellectual property rights may constitute anti-competitive behaviour as envisaged under Article 8 of the TRIPS Agreement, or for remedies under patent legislation for anti-competitive behaviour as envisioned for example under Article 31(k) of TRIPS as found in Namibia's Patent Act.⁷³¹ To date, many LMICs including those in the SADC region have experienced significant capacity constraints in reforming and using competition legislation to facilitate access to treatment.⁷³²

One opportunity for intra-regional south-south co-operation could be for South African competition officials to share with competition authorities from other SADC countries how the South African Competition Act and Competition Commission have been employed to regulate anti-competitive behaviour in the health and pharmaceutical sectors as well as some of the positive and negative lessons learned through the use of competition law as a mechanism to increase access to treatment. In addition to competition law, other pieces of legislation of SADC Member States

⁷²⁴ Bearing in mind that the United Republic of Tanzania has two pieces of legislation.

⁷²⁵ Section 25 (h) of the 2010 Industrial Property Act.

⁷²⁶ Section 43(2) of the 2012 Industrial Property Act.

⁷²⁷ As per Section 69.A of the Patents Act.

⁷²⁸ Section 12(4)(a)(v).

⁷²⁹ As seen in Chapter four in the discussion between compulsory licensing provisions in mainland Tanzania's patent Act of 1987 and Zanzibar's Industrial Property Act of 2008.

⁷³⁰ As per Article 8 of the Competition Act.

⁷³¹ Section 57(c) of the Patent Act provides for a compulsory license to be issued in the public interest where the Namibian Competition Commission established in terms of the Competition Act has determined that the manner of exploitation, of the patent by the owner of the patent or his or her licensee, constitutes a restrictive business practice prohibited under the Competition Act.

⁷³² See Nayak N, in UNDP (2014) for a detailed discussion of some of the capacity constraints facing competition authorities from developing countries including a number of eastern and southern African countries.

including those related to the regulation of counterfeit goods, the enforcement of intellectual property rights or the regulation of medicines may be provide opportunities to further incorporation of public health related TRIPS flexibilities as is the case in South Africa and Tanzania.

6.3 South-South: Cross Cutting Issues Relevant to Both Regions

There are a number of issues of common concern facing eastern and southern African countries regarding regional co-operation on treatment access issues. Some of these provide opportunities to deepen regional co-operation, while others are potential impediments to effective co-operation that will have to be addressed. One important question centres around whether continental efforts to increase access to health technologies through the African Union's Pharmaceutical Manufacturing Plan for Africa constitute a synergy or a duplication of sub-regional efforts at the EAC and SADC. A second consideration is the set of intellectual property concerns arising from the harmonisation of drug regulatory standards. A third set of considerations pertains to opportunities and challenges posed by intra-regional co-operation including the African Union's partnership agreements with India and China on health matters well as the impact of South Africa's membership of the BRICS⁷³³ and IBSA⁷³⁴ configurations and what implications this might have on treatment access in the eastern and southern Africa.

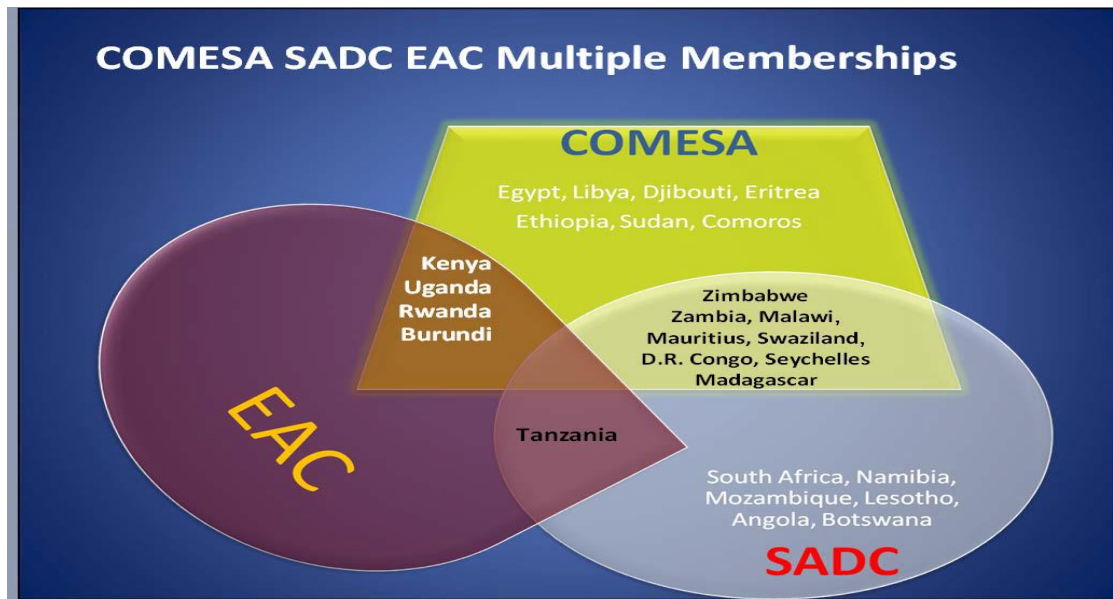
One commonality between countries in Africa is the overlapping membership of a number of countries in regional economic organisations. Aside from the EAC and SADC, several eastern and southern African countries belong to a combination of other groupings including COMESA. Four out of five EAC Partner States are also Members of COMESA. In addition, more than half of SADC Member States also belong to COMESA.⁷³⁵

⁷³³ The grouping of emerging countries comprising Brazil, China India, Russia, which South Africa was invited to join in 2011.

⁷³⁴ The country grouping of three BRICS members, Brazil, India and South Africa.

⁷³⁵ DRC, Madagascar, Malawi, Mauritius, Seychelles, Swaziland, Zambia and Zimbabwe.

Figure 8: Overlapping memberships of COMESA, EAC and SADC



While COMESA with 20 Member States is the largest of the three regional economic communities, it is also the least advanced in achieving its goals for regional co-operation on intellectual property and access to treatment. Countries that belonged to more than one of the three regional economic communities have consistently opted to leave COMESA when overlapping membership required the withdrawing from a regional economic organisation.⁷³⁶ While the EAC has a policy and a draft Protocol intellectual property and TRIPS flexibilities in place, and SADC has a Pharmaceutical Business Plan, COMESA's policy on intellectual property covers a broad subject matter including copyright, industrial property information communication technology (ICT), traditional knowledge, folklore and genetic resources. Moreover, its reference to the role of intellectual property in facilitating public health is limited to a sub-paragraph in the section on industrial property which calls on Member States to:

⁷³⁶ Lesotho and Mozambique exited COMESA in 1997, Tanzania in 2000, Namibia in 2004 and Angola suspended its membership in 2007.

“ Encourage Member States to utilize and exploit to the full the flexibilities provided in IP international treaties such as the Doha Declaration on the TRIPS Agreement and Public Health so to facilitate access to medicines for all people particularly the marginalised of society.”⁷³⁷

The same paragraph also urges Member States to enforce and protect intellectual property despite almost two thirds of COMESA’s membership comprising of LDCs.⁷³⁸ For instance, paragraph 39(c) encourages COMESA Member States to:

“Promote and encourage collaboration in protection and enforcement of industrial property, particularly the fight against production, manufacture and trade in counterfeit goods within COMESA.”

For the purposes of optimizing policy space required to promote sustainable treatment options, it remains unclear whether the national policy objectives of COMESA Member States including Burundi, Rwanda, Uganda and Zanzibar who have taken steps to incorporating public health related TRIPS flexibilities into national legislation would be undermined by their membership of COMESA. It is even more important that national and intra-regional initiatives in SADC and the EAC are synergistic with regional initiatives being undertaken by the African Union as will be discussed below.

6.3.1 The Pharmaceutical Manufacturing Plan for Africa: Opportunities and Challenges

As discussed above in chapter one, sub-Saharan Africa shoulders a disproportionately large global disease burden for HIV,⁷³⁹ TB, and malaria as well as a growing prevalence of NCDs. According to projections,⁷⁴⁰ by 2030, if current trends around the retention of patients in current AIDS treatment programmes continue, an increase in ischaemic heart disease, cerebrovascular disease

⁷³⁷ Paragraph 39(d) of the intellectual property policy [Online] Available: <http://www.ip-watch.org/weblog/wp-content/uploads/2013/05/Comesa-IP-policy-May-2013.pdf>

⁷³⁸ Angola, Burundi, Comoros, Djibouti, DRC, Eritrea, Ethiopia, Madagascar, Malawi, Sudan, Uganda and Zambia.

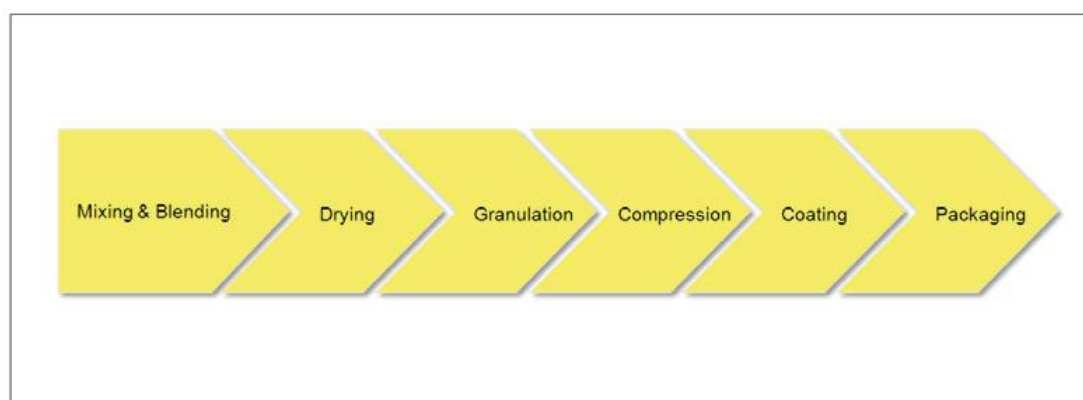
⁷³⁹ Approximately 75 percent of AIDS deaths occur in Africa. In addition, nine African countries rank among the 15 countries with the global TB burden according to the WHO Global Tuberculosis Report of 2011.

⁷⁴⁰ See Mathers D, and Loncar D, (2006) ‘Projections of Global Mortality and Burden of Disease from 2002 to 2030.’ PLOS Med 3(11): e442, [Online] Available: <http://www.plosmedicine.org/article/info:doi/10.1371/journal.pmed.0030442>

(stroke), and chronic obstructive pulmonary disease (COPD) will make NCDs the leading cause of death on the continent.

The AU's projections are that the growing health needs mentioned above combined with a projected economic growth on the continent and other favourable factors such as the expected expiry of several patents on key medicines will create conditions where rapid growth in the pharmaceutical industry can be expected.⁷⁴¹ At present, African countries remain large net importers of medicines and APIs with an estimated 95 percent of APIs and 75 percent of finished products consumed on the continent being imported. While an estimated 38 countries engage in some form of local pharmaceutical production ranging from granulation, packaging or formulations only two countries, South Africa and Egypt have the capacity to produce APIs.⁷⁴²

Figure 9: The Various Stages of Pharmaceutical Manufacturing



Source: PMPA Business Plan

⁷⁴¹ See the African Union and UNIDO (2012) 'The Pharmaceutical Manufacturing Plan for Africa: Business Plan', [Online] Available: http://www.unido.org/fileadmin/user_media_upgrade/Resources/Publications/Pharmaceuticals/PMPA_Business_Plan_Nov2012_ebook.PDF

⁷⁴² Ibid PMPA Business Plan at 31. A large variation in capacity is reported among the 38 countries with Nigeria accounting for 200 registered pharmaceutical manufacturers, with Algeria, Ghana, Kenya, South Africa and Tunisia registering between 20 and 40 local manufacturers. The next tier of countries including, Tanzania, Uganda, Zambia and Zimbabwe have between five to ten active companies.

The AU Heads of State took the political decision in 2005⁷⁴³ to develop a plan of action to promote pharmaceutical production on the continent and endorsed an initial plan in July 2007. Once political endorsement was obtained, the AU Commission (AUC) primarily assisted by UNIDO, formed a consortium to develop a more detailed Business Plan to implement the PMPA.⁷⁴⁴ Developed on the premise that the right to the highest standard of health is a fundamental human right,⁷⁴⁵ and with the realisation that there was a shrinking donor pool available for the AIDS response⁷⁴⁶ the core aims and objectives of PMPA are to support the development of a pharmaceutical industry to increase access to affordable quality medicines, to ensure sustainable supply of essential medicines to improve public health outcomes to promote industrial and economic development.⁷⁴⁷

The role of intellectual property as both a facilitator and an impediment in meeting the objectives of the PMPA are recognised by the AUC. In noting that not enough countries have incorporated public health related TRIPS flexibilities into national legislation, and that a number of LDCs in the region have exceeded their obligations under the TRIPS Agreement, the PMPA Business plan notes that:

*“One of the key policy and legislative changes needed in order to benefit our continent, its patients and local industry is in the domain of intellectual property rights.”*⁷⁴⁸

The PMPA Business plan reveals the intention of the AUC to work in partnership with ARIPO, UNCTAD and UNDP in part to lobby for simplification of the means by which flexibilities can be exploited and to advise and assist governments to revise and amend their patent laws to incorporate

⁷⁴³ As per the AU Assembly Decision (Assembly/Dec.55 (IV), adopted in Abuja in January 2005. The AU is a continental organisation with 54 out of 55 African countries listed as Member States. Morocco left the AU in 1984 because of the organisation’s recognition of the Sahrawi Arab Democratic Republic.

⁷⁴⁴ At the request of African Ministers of Health at a meeting held in Namibia in 2011.

⁷⁴⁵ Ibid PMPA page 18.

⁷⁴⁶ See UNAIDS and the Kaiser Foundation (2011) ‘Financing the Response to AIDS in Low- and Middle- Income Countries: International Assistance from Donor Governments in 2010’ [Online] Available: <http://kaiserfamilyfoundation.files.wordpress.com/2013/01/7347-07.pdf>

⁷⁴⁷ Ibid PMPA page 18. While it is expected that the aims and objectives of the PMPA are long term (in excess of 15 years), it is expected that significant progress can be made in the first phase of the plan which commenced in 2013 and is expected to last for the next five years.

⁷⁴⁸ Ibid PMPA page 79.

the flexibilities, assist international GMP compliant Africa based companies wishing to make full use of the flexibilities in order to supply LDC markets and to work with RECs to harmonize national patent laws to facilitate exploitation of the flexibilities for the benefit of the continent.⁷⁴⁹

The PMPA operates in tandem with the AU's Roadmap on Shared Responsibility and Global Solidarity for the AIDS, TB and Malaria Response in Africa,⁷⁵⁰ a document developed to provide a pathway for African countries to effectively respond to large disease burdens. Developed in response to the global economic crisis of the late 2000s, which has resulted in decreased funding for the AIDS response in Africa,⁷⁵¹ the Roadmap acknowledges that multilateral aid budgets will continue to be in decline for the foreseeable future.⁷⁵² The Roadmap also acknowledges the potential impact of India's implementation of the TRIPS Agreement on the sustainability of treatment programmes. The Roadmap also concedes that as an 'emergency style approach to AIDS' is coming to an end and that with the nearing of 2015, the deadline set for countries to meet their MDG targets, countries will be consolidating gains made in responding to AIDS, TB and malaria into broader health goals.⁷⁵³

The Roadmap is premised on three pillars, the second of which makes important intellectual property recommendations for AU Members including explicit encouragement to create legislative environments that fully incorporate public health related TRIPS flexibilities while avoiding "TRIPS-plus" commitments in trade agreements. This recommendation is expected to assist in keeping treatment sustainable while the continent's reliance on Indian pharmaceutical products is gradually off-set by an anticipated increase in continental pharmaceutical production. While the Roadmap provides important strategic direction and advice to countries, responsibility remains with the AU Member States to implement elements of the Roadmap including those relating to

⁷⁴⁹ Ibid, pages 79-80 of PMPA.

⁷⁵⁰ In January 2012, the AU Assembly Decision No: Assembly/AU/Dec.413 (XVIII), requested the AUC "*to work out a roadmap of shared responsibility to draw on African efforts for a viable health funding with support of traditional and emerging partners to address AIDS dependency response*"

⁷⁵¹ Page 7 of the Roadmap notes that as of 2012, in 27 African countries, 84 percent of expenditures for ART originated from international sources. It is also noted that the decline in multilateral funding resulted in the unprecedented cancellation of Round 11 of the Global Fund as a result of the Fund not having met its replenishment targets.

⁷⁵² According to the Roadmap, China became Africa's number-one trading partner in 2009, and other emerging economies, including Brazil and India, now account for 37 percent of Africa's trade.

⁷⁵³ See page 10 of the Roadmap for a more detailed discussion on the shift from AIDS exceptionalism into broader health outcomes.

intellectual property. The Roadmap also provides strategic direction over a continental initiative to harmonise the rules of drug regulatory authorities on the continent as will briefly be discussed next.

The PMPA and the AU Roadmap complement sub-regional efforts at the EAC and SADC aimed at facilitating increased access to health technologies. However, there are also a number of areas where policy incoherence at the regional level may undermine efforts to increase access to a sustainable supply of health technologies. The intellectual property protocols, policies and practices of the ARIPO do not appear to complement regional and continental initiatives on access to medicines as discussed below. In addition, two continental initiatives appear to provide contrary advice to countries regarding the incorporation and use of public health related TRIPS flexibilities, which may impede the availability of affordable health technologies. These are discussed next:

(i) The African Medicines Regulatory Harmonization Initiative

In the same way that local pharmaceutical production is expected to benefit from a co-ordinated intellectual property policy framework, there are obvious advantages in increased co-operation among DRAs. It comes as little surprise then that, the PMPA and the AU Roadmap⁷⁵⁴ advocate for increased investments to improve the capacity of DRAs in regulating the quality, safety and efficacy of medicines manufactured in African countries. An initiative to increase intra-regional co-operation between DRAs commenced shortly after the PMPA was adopted. The African Medicines Regulatory Harmonization Initiative (AMRHI) was established in 2009 with the intention to improve health in the Region by increasing access to safe and effective medicines of good quality. The AMRHI aims to do this by strengthening the technical and administrative capacity of participating national medicines regulatory authorities. In so doing, the project will lead to the development of collaborative networks of national and regional drug regulatory authorities; the harmonization of technical standards and the establishment of a framework for joint evaluations of application dossiers and inspections of medicine manufacturing sites.⁷⁵⁵

⁷⁵⁴ See paragraphs 54 and 55 of the AU Roadmap for more information.

⁷⁵⁵ As per the World Health Organisation's website on international co-operation and harmonization on medicines [Online] Available: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/harmonization/en/index.html

A key outcome of the AU's efforts to increase co-operation on medicines regulation has been the emergence of a Draft Preliminary Model Law on Medicines Regulation Harmonization in January 2013. While developed with the intention of assisting AU Members to meet their obligations in improving access to medicines⁷⁵⁶ the Draft Preliminary Model law contains a number of intellectual property provisions that may end having the opposite impact.⁷⁵⁷ For example, Sections 177-179, appear to impose an obligation on DRAs to determine the patent status of medicines before granting marketing authorization.⁷⁵⁸ As discussed above in Chapter two creating linkages between the patent status of medicines and marketing approval can pose a serious problem for DRAs, especially as patent searches can be time consuming, cumbersome and expensive. Second, Section 197 appears to impose a form of pharmaceutical test data protection that exceeds the requirements imposed on WTO Members by Article 39.3 of TRIPS. The section notes that:

“Where the Agency receives, or has received not more than 5 years before the commencement of this Law a product application in respect of an innovative medicine and confidential supporting information, the Agency, during the protected period in relation to that confidential supporting information —

- i. shall take reasonable steps to ensure that that confidential supporting information is kept confidential to the Agency; and*
- ii. shall not use that confidential supporting information for the purposes of determining whether to grant any other application.*

⁷⁵⁶ Page 2 of the Preliminary Draft Model Law notes that AU Members are:

“Convinced further that the adoption of a model law on medicines regulation in Africa is essential to the fulfilment of the mandate of the African Union to promote and protect human and peoples’ rights in accordance with Article 45 of the African Charter on Human and Peoples’ Rights”

⁷⁵⁷ An extensive critique of the Preliminary Draft Model Law has been undertaken by Baker B, Gray A, and Vadwa Y, in an unpublished 2013 paper (on file with author).

⁷⁵⁸ Section 177 for instance reads:

“In dealing with an application for a product licence, the Agency –

- i. shall consider whether a patent under any existing patent law in the country is in force in respect of any medicine to which the application relates;*
- ii. shall further consider whether the applicant is the proprietor of the patent; and*
- iii. may rely upon, and shall not be concerned to inquire into the truth of any statement made in the declaration regarding the existence, non-existence or invalidity of a patent in respect of the drug.*

Unless the Agency otherwise determines, an applicant for a product licence shall, at the time of their application and at such other time as the Agency may require, make and furnish to the Agency a declaration in the prescribed form stating whether a patent under any law in the country on patents is in force in respect of any medicine to which the application relates.”

As discussed in chapter two, data exclusivity could result a *de facto* monopoly on test data for the originator company or additional costs having to be incurred by a generic manufacturer wishing to obtain marketing approval. As both outcomes impede competition, this provision seeks to undermine the goals of the PMPA and AU Roadmap.

(ii) The Pan African Intellectual Property Organisation

Another ostensibly well intentioned initiative which may have long lasting negative implications on access on treatment access in the region is the recently established PAIPO. Following a decision⁷⁵⁹ in 2007 by African Heads of State to establish a continental Intellectual Property organisation, African Ministries of Science and Technology took the lead in efforts to establish a single African intellectual property agency without involvement of the Ministries of Trade or Health. It is unclear why the AU did not mandate ministries of trade and industry, traditionally the custodians of intellectual property matters, to oversee the establishment of the PAIPO. The AU Scientific, Technical and Research Commission developed the enabling legislation statutes of this new entity with a validation exercise at a stakeholder's Workshop in 2011, in Senegal. The final draft of the PAIPO statutes was submitted to AU Member States. In January 2013, the AU Heads of Summit ended with a decision to establish the PAIPO.⁷⁶⁰

According to the Final Draft PAIPO Statute,⁷⁶¹ one of the functions of the organisation will be to:

“Take deliberate measures to promote the protection and exploitation of Intellectual Property rights within the Member States, including conclusion of bilateral and multilateral agreements.”

⁷⁶²

⁷⁵⁹ (Assembly Council/AU/Dec. 138(VIII)).

⁷⁶⁰ This, according to a press-release following the conclusion of the 20th AU Summit dated 28 January 2012 [Online] Available:

<http://summits.au.int/en/sites/default/files/PR%20N%2020%20CLOSING%20OF%20TH%20AU%20SUMMIT%2028%2001%2013%20f.pdf>

⁷⁶¹ See the Final Draft statute of the Pan African Intellectual Property Organisation, Document number: AU/STRC/522.

⁷⁶² Article 5(iii).

This provision infers that intellectual property protection and enforcement are the objective of PAIPO rather than the use of intellectual property flexibilities to increase access to treatment. Recent developments such as the adoption of the PMPA, as well as the EAC policy on TRIPS flexibilities, the SADC Pharmaceutical Business Plan together with the fact that WTO Members have exempted LDCs from having to apply the TRIPS Agreement until 1 July 2021 could be seen as a clear sign that a key priority for an a regional organisation in which more than half the membership are classified as LDCs⁷⁶³ should be to maintain policy space needed by its membership around intellectual property. There is problematic language elsewhere in the draft PAIPO statute which notes that another objective of the recently established organisation is to:

*“Initiate activities that strengthen the human, financial and technical capacity of Member States to maximize the benefits of the intellectual property system to improve public health and eradicate the scourge of piracy and counterfeits on the continent.”*⁷⁶⁴

These provisions as well as one noting that PAIPO will formulate a common negotiating position for Africa countries in international trade negotiations⁷⁶⁵ could easily impede rather than enable of intra-regional co-operation on access to health technologies. Nothing in the draft statute acknowledges the potential impediment posed by overly broad anti-counterfeiting legislation at the EAC on access to treatment, nor does it appear to distinguish between the different positions on intellectual property that might be needed by a regional organisation with a membership as diverse as South Africa and Egypt on one hand and Burundi or the DRC on the other.

For reasons discussed above, the regional initiatives of the AMRHI and PAIPO, which are primarily aimed at promoting regional co-operation among Member States of the African Union are also examples of how policy incoherence if unaddressed, would undermine efforts to increase regional co-operation in the trade of health technologies as postulated by the third hypothesis of the thesis. In the case of PAIPO, the degree of incoherence and lack of involvement in its

⁷⁶³ 33 of the world's 48 LDCs are in Africa.

⁷⁶⁴ Article 5(vi).

⁷⁶⁵ Article 5(viii).

establishment and operation is validated by the emergence of a communiqué⁷⁶⁶ adopted by the Chairmen of ARIPO and OAPI in Harare in April 2014, which among other things notes:

“... the fact that the Ministers responsible for Intellectual Property issues/matters in African countries have not been consulted and involved in the AMCOST meetings” and requests the African Ministers of Science and Technology to “(a)to convene the Stakeholders Meeting as a matter of urgency to enable the participation of all stakeholders including ARIPO, OAPI and WIPO, and (b)for the Ministries/competent authorities responsible for IP to play a leading role in the process of establishing PAIPO.”

In addition to the involvement of ministries of trade or the authorities responsible for the administration of intellectual property, one might assume too that it would be important that the Ministries of health and other authorities responsible for the implementation of both sub-regional and regional initiatives aimed at increasing a sustainable supply of affordable health technologies such as the EAC RPMPoA, SADC Pharmaceutical Business Plan and the AU’s PMPA, be closely consulted and afforded the opportunity to input into the PAIPO final statute. Moreover, AU Member States may wish to pay close attention to ensuring that the content of the draft PAIPO statute does not undermine the aims and objectives of the regional and sub-regional initiatives discussed above.

6.3.2 The impact of ARIPO on the use of TRIPS Flexibilities by its Member States

Another key determinant of whether eastern and southern African countries will use public health related TRIPS flexibilities to increase access health technologies rests with the enabling statutes and regulations of ARIPO, and the practices of its Secretariat. As noted above in Chapter four, ARIPO is one of two regional intellectual property organisations in Africa which examines, grants and administers patents, utility models and industrial designs on behalf of its Member States. ARIPO is the regional organisation of choice for Anglophone countries while OAPI administers, examines and grants patents on behalf of 17 Francophone African countries. Several Member

⁷⁶⁶ The full text of the communiqué is [Online] Available: <http://www.aripo.org/index.php/news-events/press-room/323-communique-adopted-by-the-joint-meeting-of-the-chairmen-of-aripo-and-oapi-held-at-the-headquarters-of-aripo-on-april-10-and-11-2014-harare-republic-of-zimbabwe>

States rely on the ARIPO Secretariat to conduct substantive pharmaceutical examinations on their behalf. A number of observer countries also seek technical advice from the ARIPO Secretariat on substantive patent examinations

As discussed in Chapter four, there are benefits to a patent applicant who, by filing one application form with the ARIPO Secretariat,⁷⁶⁷ can elect to file the application in all ARIPO Member States. The current mechanism may be problematic for Member States on both substantive and procedural grounds. The primary procedural concern is the limited timeline available to Member States to respond to patent applications. While countries ultimately retain the right to choose whether or not to agree with a decision of the ARIPO Secretariat to grant a patent, the Harare Protocol places the onus on the Member State to notify the Secretariat in writing within six months of the patent having been granted that it is not valid in the territory of Member State. The following grounds may be given by a Member State for patent invalidation:

- (i) The invention is not patentable in accordance with the provisions of the Harare Protocol; or
- (ii) That, because of the nature of the invention, a patent cannot be registered or granted or has no effect under the national law of that State.⁷⁶⁸

If no objection is received from a Member State within the prescribed six month period, the ARIPO Secretariat shall grant and publish the patent which will be valid in all Member States the applicant had designated on the application form.⁷⁶⁹ This procedure places a duty on ARIPO Member States to examine a pharmaceutical patent application within a relatively short period of time upon being notified of its examination by patent examiners at the ARIPO Secretariat. Depending on the capacity of a national patent office, six months is highly unlikely to be a sufficiently long period of time within which to substantively examine a patent application and to make a determination as to whether the application merits the granting of a patent. The average time from filing to grant of a patent in the European Patent Office was reportedly was almost 44 months at the end of 2007.⁷⁷⁰

⁷⁶⁷ Section 2 of the Harare Protocol.

⁷⁶⁸ According to Section 3 (6) of the Harare Protocol.

⁷⁶⁹ As per Section 3(7) of the Harare Protocol.

⁷⁷⁰ According to the 2007 Annual Report of the EPO [Online] Available: <http://www.epo.org/about-us/annual-reports-statistics/annual-report/2007/statistics.html>

Another example of the challenges that may occur because of the presumption that a granted patent is valid unless a country declares otherwise, is the case of Ghana. Patent examiners in ARIPO granted a number of patent applications filed by the originator pharmaceutical company Glaxo Welcome⁷⁷¹ in October 1997 for combivir, a combination of two existing ARVs zidovudine and lamivudine.⁷⁷² Despite the fact that pharmaceutical products were not patentable under Ghanaian law at the time, Glaxo Welcome was able to disrupt the distribution in Ghana of a more affordable generic version of combivir produced by Cipla on the basis of the ARIPO patent.⁷⁷³ One way to resolve such episodes from re-occurring would be to lengthen the notification period well beyond six months. Another could be to reverse the onus the Harare Protocol places on countries by providing them a limited period of time within which to ratify patents granted by ARIPO. Another would be to remove LDCs from the list of ARIPO Member States where patent applications can be filed for through the Harare Protocol.

There are a number of substantive concerns regarding the potential impact of the Harare Protocol on the ability of ARIPO Member States to use public health related TRIPS flexibilities. First, the majority of patents being granted by the ARIPO Secretariat are to foreign applicants, According to WIPO, of the 435 patents granted by ARIPO in 2008, a mere 11 were from residents of ARIPO Member States.⁷⁷⁴ Moreover, according to the WIPO patent database PATENTSCOPE, pharmaceuticals and organic fine chemistry accounted for almost 46 percent of all non-resident patent applications at the ARIPO Secretariat during the same time period.⁷⁷⁵

This begs the question whether the public health interests of ARIPO Member States should be prioritised by the tightening of criteria for patentability and to focus on increasing access to health technologies as opposed to the granting of patents which may serve as a basis to keep medicine

⁷⁷¹ Glaxo Welcome merged with the originator company and SmithKline Beecham in 2000.

⁷⁷² Oxfam (2001) '*Dare to Lead: Public Health and Company Wealth*', Briefing Paper on GlaxoSmithKline

⁷⁷³ Ibid Oxfam at 22. A Wall Street Journal Article from 1 December 2000 '*Glaxo attempts to block access to generic AIDS drugs in Ghana*' cited the then Chief patent examiner from ARIPO as saying that Glaxo would lose any action it took to enforce those patents in Ghana.

⁷⁷⁴ As per information obtained from WIPO's statistical database in Marongiu A, (2011) 'Non-Resident Patent Applications in the African Regional Intellectual Property Organization' Mile 11 Thesis, World Trade Institute, Berne [Online] Available: http://www.wti.org/fileadmin/user_upload/wti.org/1_master-programme/pdfs/Masters_thesis_Alessandro%20Marongiu.pdf

⁷⁷⁵ Ibid Marongiu at 32.

prices high. It should be remembered that 13 of the 19 ARIPO Member States are LDCs and that a number of them including Rwanda, Uganda and Zanzibar have chosen to exempt pharmaceutical products from patentability under existing legislation while Zambia has incorporated the exemption into draft legislation.⁷⁷⁶ The harmonisation of the Harare Protocol with the development objectives of a number of ARIPO Member States would appear to be a matter of urgent priority.

The second and more serious issue the Harare Protocol highlights is the discrepancy in how TRIPS flexibilities may be incorporated and used by the ARIPO Secretariat and its Member States. One such example relates to the criteria for patentability. On the face of it, the Harare Protocol appears to have adopted the same requirements imposed by Article 27.1 of TRIPS around novelty, inventive step and industrial applicability.⁷⁷⁷ However, in practice, some patents granted by officials at ARIPO clearly involve a lax rather than strict interpretation of Article 27.1 of TRIPS, which may be inconsistent with the public health interests of several Member States. For instance, Section 3(10) of the Harare Protocol in defining novelty excludes from the definition of prior art:

“disclosure of the invention at an official or officially recognized exhibition shall not be taken into consideration if it occurred not more than six months before the date of filing of the application or, if priority is claimed, before the priority date validly claimed in respect thereof”

This is a narrow definition of prior art and in contrast to the definitions adopted by ARIPO Member States such as Zanzibar have in a provision on inventive step introduced a requirement that the invention must not have been obvious to someone highly skilled in the art.⁷⁷⁸ The implications of lax patentability criteria are evident from the granting of patents to Glaxo Wellcome for combivir, which as noted a combination of two existing molecules. A number of patent offices in LMICs including Brazil, China, Guatemala and Ukraine, did not grant a patent for combivir.⁷⁷⁹ In the case of India, GSK withdrew a patent application for combivir in 2006 on the basis of a patent

⁷⁷⁶ On file with author.

⁷⁷⁷ According to Section 3(10):

“Inventions for which patents are granted by the Office shall be new, shall involve an inventive step and shall be industrially applicable.”

⁷⁷⁸ Section 4(3) of the Patent Act of 2008.

⁷⁷⁹ See Boulet P, Garrison C and t’hoen E (2003) ‘Drug Patents Under the Spotlight’, Médecins Sans Frontières at Annex A [Online] available: <http://apps.who.int/medicinedocs/en/d/Js4913e/>

opposition filed by treatment groups after the passing of the Indian Patents Act of 2005, containing Section 3(d). A number of countries in the EAC and SADC have either adopted or are considering the adoption of criteria stricter than those being used by the ARIPO Secretariat, and should be able to exercise national priorities should they so wish, as opposed to the ‘one size fits all’ approach being implemented by the Harare Protocol at present.

Another example of how public health related TRIPS flexibilities have not been sufficiently incorporated into the Harare Protocol is the absence of a provision enabling oppositions to patent applications both before and after the grant of the patent. The Harare Protocol contains a provision which attempts to provide a general limitation to patent rights by noting that:

“A patent granted by the Office shall in each designated State be subject to provisions of the applicable national law on compulsory licenses, forfeiture or the use of patented inventions in the public interest”

However, some of eastern and southern African territories that are ARIPO Member States including Zanzibar⁷⁸⁰ provide for pre-and post-grant patent oppositions by interested third parties, while many others provide for post-grant oppositions.⁷⁸¹ The right of interested third parties to file pre-and post-grant patent opposition proceedings should be reflected in the Harare Protocol as a key flexibility particularly given the potentially wide-ranging geographical applicability of an ARIPO patent once granted as well as the obvious public health implications given the high burdens of disease in the region.

6.3.3 Cross-regional co-operation between African Countries and emerging economies of the South

While this chapter has to date focused on intra-regional co-operation on intellectual property and access to health technologies, this section will discuss opportunities for individual countries in

⁷⁸⁰ Section 10(7)(a) of the Patent Act.

⁷⁸¹ Including Kenya, Mainland Tanzania and Uganda.

eastern and southern Africa as well as the AU to co-operate with other large developing countries with similar priorities. There are both public and private sector opportunities for south-south co-operation on access to treatment, albeit in different ways.

An example of private sector south-south co-operation on access to treatment is the recent partnership between the Indian pharmaceutical giant Cipla and Quality Chemicals, a Ugandan generic pharmaceutical manufacturing company. In February 2012, news agencies reported that Quality Chemicals, a WHO-pre-qualified pharmaceutical manufacturer which is a joint venture between Cipla, and the Ugandan government, was to commence with the production of ARVs to treat HIV as well as anti-malarial medicines.⁷⁸² Quality Chemicals also has the capacity to produce other ARVs including lamivudine, nevirapine zidovudine and efavirenz⁷⁸³ and is planning to produce newer generation medicines in the medium term. Quality Chemicals appears to a number of factors in its advantage which should aid its success. It has managed to obtain WHO pre-qualification which makes its products eligible for procurement by GFATM financed tenders. Second, it is situated in an LDC, and in a regional economic organisation where the use of the TRIPS flexibilities has been promoted. Third, given the role of the Ugandan government in its establishment, it appears to have high level political support. A final key advantage for Quality Chemicals must be the recent assent by the President of Uganda to the Industrial property Act⁷⁸⁴ in January 2014, which contains a number of important flexibilities, not least of all, an exemption for pharmaceutical patents until 2016 or a later date as extended by the TRIPS Council.⁷⁸⁵ Aside from private sector partnerships involving developing country companies and governments, inter-regional south-south co-operation usually takes the form of governmental co-operation as will be discussed further below.

⁷⁸² See news story from New Vision *Uganda makes new AIDS drug*, 8 February 2012 [Online] available: <http://www.newvision.co.ug/news/628873-uganda-makes-new-aids-drug.html>. See also an article from Xinhuanet, *Uganda to make new low cost HIV/AIDS drug*, 8 February 2012 [Online] Available: http://news.xinhuanet.com/english/health/2012-02/08/c_131398948.htm

⁷⁸³ According to the website of Quality Chemicals:
http://www.qcil.co.ug/index.php?option=com_k2&view=item&layout=item&id=12&Itemid=62

⁷⁸⁴ Act passed by Parliament in 2013.

⁷⁸⁵ Article 8(3)(f) excludes from patentability, pharmaceutical products and test data.

(i) Africa's Health partnerships with India, China and Brazil

There is a long history of co-operation between African countries and India dating back to the days of the Non Aligned Movement (NAM),⁷⁸⁶ and the formation of the Group of 77 (G77) at the UN.⁷⁸⁷ The first formal framework of co-operation between the two partners has its origins in the Indian Technical and Economic Cooperation Programme (ITEC), launched in 1964 and still in existence today.⁷⁸⁸ Recent years have seen a sharp increase in the volume and value of trade between the two partners with a projection of US\$ 90 billion in trade by 2015.⁷⁸⁹ Since 2008, the Government of India and the African Union have agreed on a Framework for Cooperation to guide their efforts to assist each other to achieve inclusive growth, socio-economic development and self-reliance. In the 2011 Framework for Enhanced Cooperation, the governments re-affirmed their commitment to cooperate, including in the areas of science and technology, health and access to treatment, which they specifically made the commitment:

*“to enhance collaboration in the application of advancement in science, technology, research and development to training in the area of HIV, TB and Malaria... strengthening of public-private sector collaboration in the areas of pharmaceutical and procurement in Africa and India in the framework of the Pharmaceutical Manufacturing Plan for Africa and the fight against counterfeit medicines. They also undertake to pursue dialogue on intellectual property rights and access to medicines; research and development in traditional medicine and practices in Africa and India”*⁷⁹⁰

⁷⁸⁶ The Non Aligned Movement was established as newly independent countries from Africa, Asia, Latin America and other regions in the wake of the post-colonial era as a way for so called third world countries to pursue joint policies in international forums. The first the First Summit, was held in Belgrade in 1961, with the then leaders of Egypt, Indonesia, India and Yugoslavia playing a key role.

⁷⁸⁷ The Group of 77 is a grouping of developing countries established to articulate and advocate the collective positions of its members. Established in 1964, the Group co-ordinates negotiating positions across an array of international economic and development issues within the United Nations system, and promote South-South cooperation for development. See the website for more information [Online] Available: <http://www.g77.org/doc/>

⁷⁸⁸ ITEC resources have been used over the past few decades to promote south-south capacity development in a wide range of sectors and in several forums including the AU, the United Nations Economic Commission for Africa (UNECA) and at the WTO.

⁷⁸⁹ According to the Indian Ministry of External Affairs (MEA).

⁷⁹⁰ See paragraph 5.1 of the Outcome Document of the Second Africa-India Forum Summit 2011: Africa-India Framework for Enhanced Cooperation, Addis Ababa, May 2011 [Online] Available: <http://mea.gov.in/bilateral-documents.htm?dtl/34/Second+AfricaIndia+Forum+Summit+2011+AfricaIndia+Framework+for+Enhanced+Cooperation>

Much like India, Brazil has a long history of co-operating with African countries in several platforms including the UN, the G77 and the NAM. While there is continental co-operation, Brazil has tended to focus its efforts on public health on Portuguese speaking countries with south-south co-operation programmes ongoing in Angola, Cape Verde, Guinea Bissau, Mozambique as well as São Tomé and Príncipe.⁷⁹¹ Unlike the partnerships involving Cipla, the channels of co-operation between Brazil and African countries have been in the public sector. A key agency involved in public health co-operation include the Oswaldo Cruz Foundation (FIOCRUZ), an institution housed within the ministry of health and working on a wide array of issues including pharmaceutical R&D, and local production for HIV, TB, viral hepatitis and NTDs.⁷⁹² In 2008, Fiocruz established its first international representative abroad in Maputo, Mozambique to coordinate, monitor and evaluate programs of cooperation between Brazil and Portuguese speaking African countries on a variety of matters including, transfer of technology, and other systems strengthen the health systems of partner countries.⁷⁹³

On access to medicines related issues, the government of Brazil has supported drug donations and provided technical support to national AIDS programmes in Guinea Bissau and São Tomé and Príncipe. But it is in Mozambique where the government has made its largest commitment by supporting the establishment of a local pharmaceutical production facility at a cost of at least US\$ 34.6 million, excluding the costs technical assistance from Brazilian experts. While the project had been in discussion since 2003 with the signing of a co-operation agreement between the then leaders of Brazil and Mozambique⁷⁹⁴ it was six years later that tangible progress occurred with approval of the project being obtained in 2009 by the Brazilian Senate approved its implementation. According to the Foundation for Scientific and Technological Development in

⁷⁹¹ For a table of ongoing health related activities between Brazil and African countries, see Russo G, Cabral L and Ferrinho P (2013) 'Brazil-Africa technical cooperation in health: what's its relevance to the post-Busan debate on 'aid effectiveness?' *Globalization and Health* 9:2 doi:10.1186 [Online] Available: <http://www.globalizationandhealth.com/content/9/1/2>

⁷⁹² According to its website, the Drug Technology Institute within Fiocruz known as Farmanguinhos locally produces nearly 40 percent of the medicines purchased by the Ministry of Health but accounts for only 5 percent of the costs associated with procuring medicines. More information is available from the Fiocruz website at: <http://portal.fiocruz.br/en/content/production-and-innovation>

⁷⁹³ Ibid Fiocruz.

⁷⁹⁴ As documented by Licia de Oliveira, the Associate Director of the Fiocruz Office in Africa in an interview with Fiotec [Online] Available: http://www.fiotec.fiocruz.br/institucional/index.php?option=com_content&view=article&id=993:nevirapine-production-at-antiretroviral-factory-in-mozambique-should-start-in-july&catid=133&Itemid=364&lang=en

Health (FIOTEC),⁷⁹⁵ the pharmaceutical manufacturing facility was inaugurated in July 2012 and commenced production in 2013 with five products including two first generation ARVs lamivudine and zidovudine being manufactured. It is expected that in the next few years, a total of 21 medicines including six ARVs will be manufactured locally and that the site will aim to obtain WHO pre-qualification, this making it eligible for procurement by GFATM financed tenders.

China's history of co-operation with African countries dates back to the end of the colonial period as is the case with Brazil and India. Recent years have seen a rapid increase in trade to the point that China became Africa's largest trading partner, with bilateral trade estimated at US\$ 198 billion by 2012.⁷⁹⁶ Annual roundtable conferences have been held since 2010, exploring opportunities to increase trade in pharmaceutical products between China and Africa, and to discuss inter regional opportunities for co-operation. In May 2013, African and Chinese leaders met in Botswana at the fourth health Roundtable⁷⁹⁷ where issues of joint ventures for local pharmaceutical manufacturing, improving quality and safety of pharmaceutical products and transfer of technology were discussed. While these framework roundtables and conferences have not yet resulted in results similar to the pharmaceutical manufacturing factory in Mozambique or the partnership between Cipla and Quality Chemicals in Uganda, there has been a commitment by Chinese officials to support existing regional initiatives such as the PMPA and the AU Roadmap on Shared Responsibility and Global Solidarity to increase a sustainable supply of essential medicines and health technologies.⁷⁹⁸

The success of initiatives involving either involving the government and private sector from Brazil, India, China or similar economies will be partially determined by the degree to which all partners

⁷⁹⁵ See a Fiotec Press release *The first anti-retrovirals manufacturing site in Mozambique starts operations; project supported by Fiotec* of July 2012, [Online] Available:

http://www.fiotec.fiocruz.br/institucional/index.php?option=com_content&view=article&id=1077:the-first-antiretrovirals-manufacturing-site-in-mozambique-starts-operations-project-supported-by-fiotec&catid=133&Itemid=364&lang=en

⁷⁹⁶ According to a synopsis provided by the Trade Law Centre for Southern Africa (tralac), August 2013 [Online] Available: <http://www.tralac.org/files/2013/08/Africa-China-trading-relationship-Synopsis.pdf>

⁷⁹⁷ The fourth forum was co-hosted by the Ministry of Health of Botswana, Peking University and the China Chamber of Commerce for Import and Export of Medicines and Health Products, within the Chinese Ministry of Commerce.

⁷⁹⁸ According to a press statement of 16 May 2013 released after the forum [Online] Available: <http://allafrica.com/stories/201305161396.html>

retain policy space in their domestic intellectual property related legislation. Aside from drawing lessons from some of the public health sensitive sections of each other's legislation, potential collaboration between Brazil, China, India and several eastern and southern African countries may lie in increased co-ordination of common negotiating positions in forums where intellectual property matters are negotiated such as at the WTO Council for TRIPS.⁷⁹⁹ The decision in July 2013 to exempt LDCs from having to apply the TRIPS Agreement with the exception of Articles 3, 4 and 5 until July 2021, has a direct impact on the policy space required by several African countries to make south-south co-operation a success. The fact that up to 34 African countries are classified as LDCs provides great latitude should they choose to customize intellectual property legislation to better address public health objectives.

Other opportunities for increased co-operation between African countries and large economies like China Brazil and India may lie at the WTO Council for TRIPS where debates in recent years on the effectiveness of the August 30 2003 Mechanism at WTO TRIPS Council have taken place in recent years. Another area for closer co-operation during negotiations relating to intellectual property lies at the WHO, where negotiations on the use of the terms sub-standard/spurious/falsely labelled/falsified/counterfeit medical products has a direct impact on the conflation of generic and sub-standard medicines produced by emerging economies as discussed in chapter two.⁸⁰⁰ A brief discussion of new south-south co-operation configurations involving South Africa, the main driver of economic growth in the SADC region takes place.

⁷⁹⁹ This was made clear by the statement made by India at the WTO Council for TRIPS meeting on the LDC extension where a concern was raised that the negotiations took place between a small sub-set of WTO Members consisting of developed countries like the US and EU, and LDCs to the exclusion of developed countries like India. More information on the reaction of developing countries is available from IP Watch Story of 12 June 2013, '*LDCs Obtain New Waiver On IP Obligations At WTO, Take It As A Limited Victory*' [Online] Available: <http://www.ip-watch.org/2013/06/12/Ldcs-obtain-new-waiver-on-ip-obligations-at-wto-take-it-as-a-limited-victory/>

⁸⁰⁰ In light of the seizures of generic medicines in transit as discussed in chapter two and the conflation between counterfeit, sub-standard and generic medicines that has taken place in a number of places including in anti-counterfeiting legislation within the EAC, the WHA in Resolution WHA63(10) delegated a working group to assess the prevention and control of substandard/spurious/falsely labelled/ falsified/counterfeit medical products form a part of its work in the area of quality and safety of medicines. The Working Group as of July 2013 is still embroiled in negotiations. More information on the Working Group can be found [Online] Available: http://apps.who.int/gb/ssffc/e/ssffc_wg1.html.

- (ii) IBSA and BRICS configurations: what do they mean for South Africa on IP, south-south co-operation and treatment access?

South Africa is the latest addition to the BRICS configuration of countries,⁸⁰¹ which together, account for a third of the global HIV burden and almost half of the global TB burden. Three of the BRICS; India, the Russian Federation and South Africa have high and growing infections of multi-drug resistant TB;⁸⁰² and two (China and Brazil) have high levels of Hepatitis C infection.⁸⁰³ In addition, given that 80 percent of NCDs occur in LMICs⁸⁰⁴ and the BRICS accounts for half the world's population, it follows that a high priority accorded to sustainable treatment programmes among the BRICS. The importance of the matter for the BRICS has been amplified by the funding difficulties which re-shaped list of countries eligible for programming from the GFATM. This re-classification of countries led to the exclusion of Brazil, China and the Russian Federation from eligibility for Global Fund grants as of 2012.⁸⁰⁵

Co-operation on intellectual property to facilitate access to essential medicines and health technologies has been formally on the agenda BRICS meetings since the Health Ministers summit held in Beijing China in July 2011. The Health Ministers' summit culminated in a declaration reiterating the commitment of the BRICS to the WHO Global Strategy and Plan of Action (GSPoA) on Public Health, Innovation and Intellectual property⁸⁰⁶ and a desire to not allow the erosion of TRIPS flexibilities as a mechanism to increase access to health technologies. Paragraph 22 of the Declaration notes:

⁸⁰¹ The term BRIC was coined in 2001 by Goldman Sachs to refer to the large emerging economies of Brazil, Russia, India and China. At a BRIC foreign ministers meeting on 21 September 2010, it was agreed to extend an invitation to South Africa to join the group, which it did in 2011.

⁸⁰² While 82 percent of cases of HIV and TB co-infection occur in Africa, India and Russia have significant co-infections. See Floyd K, et al (2013) 'Domestic and donor financing for tuberculosis care and control in low-income and middle-income countries: an analysis of trends, 2002–11, and requirements to meet 2015 targets' *Lancet Global Health*, Vol 1, Issue 2 105-115 [Online] Available:

<http://www.sciencedirect.com/science/article/pii/S2214109X13700329>

⁸⁰³ China is said to have more cases of Hepatitis C than all of Europe.

⁸⁰⁴ As per the communique issued by the BRICS Ministers of Health following their summit meeting in New Delhi in January 2013 [Online] Available: <http://pib.nic.in/newsite/erelease.aspx?relid=91533>

⁸⁰⁵ The 25th Global Fund Board meeting held in November 2011 in Accra, Ghana took the decision to exclude upper middle income countries that do not have extreme burdens of disease from funding as of 2012. This affected several countries including Argentina, Brazil, China, Mexico and the Russian Federation.

⁸⁰⁶ See paragraph 18 of the Declaration [Online] Available: <http://keionline.org/node/1183>

“We are determined to ensure that bilateral and regional trade agreements do not undermine TRIPS flexibilities. We support the TRIPS safeguards and are committed to work together with other developing countries to preserve and promote, to the full, the provisions contained in the Doha Declaration on TRIPS and Public Health and of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.... In addition, we support the development of innovative mechanisms of transfer of intellectual property rights for priority technologies, to open avenues for BRICS countries to supply these medicines to low and middle income countries”

The BRICS health Ministers met again in January 2013 in New Delhi, India and re-affirmed their commitment to pursue south-south co-operation South-South cooperation and to support efforts in developing countries to promote health for all. The commitment of the Ministers of Health to south-south co-operation and the use of public health related TRIPS flexibilities to facilitate access to health technologies was again re-iterated at the Health Ministers’ meeting at the margins of the 2014 WHA in May. It should be noted that despite the communiques from the Ministers of health, more formal co-operation among the BRICS has taken place at meetings between ministers of trade. At a meeting in Durban, South Africa, in March 2013, the ministers of trade concluded a Trade and Investment Co-operation Framework Agreement⁸⁰⁷ which commits them to co-operate on matters of mutual concern at multilateral forums at the WTO and elsewhere. On intellectual property, the ministers committed to enhancing information exchange on intellectual property legislation and enforcement through meetings or seminars, jointly developing capacity building programmes on intellectual property and promoting cooperation among intellectual property offices.⁸⁰⁸

What is not clear from the Framework concluded by the Ministers of Trade and the communiques issued by the Ministers of Health is the degree to which there is inter-sectoral co-ordination between the various branches of government. There are different levels of intellectual property protection and enforcement among the BRICS with implications on access to medicines. As part

⁸⁰⁷ The Full text of the 2013 BRICS Trade and Investment Framework is available [Online] at: <http://www.ip-watch.org/weblog/wp-content/uploads/2013/03/BRICS-Trade-and-Investment-Cooperation-Framework-25-.pdf>

⁸⁰⁸ As per paragraphs 4.5 of the Declaration.

of their WTO accession commitments, both China⁸⁰⁹ and Russia⁸¹⁰ are required to implement data exclusivity despite this not being required by Article 39.3 of TRIPS.⁸¹¹ While there may be a few areas for inter-regional co-ordination among member of the BRICS, there are sufficient differences to prevent a completely integrated level of co-operation.

There are however, opportunities to share experiences among the BRICS on fully incorporating public health related TRIPS flexibilities into national legislation and how this can result in increases access to essential medicines and health technologies. Examples of progressive use of public health related TRIPS flexibilities already discussed above include India's implementation of Article 27 (1) of the TRIPS Agreement with the enactment of Section 3(d) of the Patent Act, the participation of the drug regulatory agency in Brazil in the examination of pharmaceutical patents, the grant of compulsory licenses in India and Brazil,⁸¹² and the role of the Competition Commission in South Africa in regulating anti-competitive conduct as well as that of the Indian Patent Office to grant a compulsory licence for the cancer medicine Sorafenib. Some of the examples of patentability criteria may be of interest in Brazil given the commencement of an ambitious initiative to reform a number of Brazil's intellectual property legislation⁸¹³ with implications on TRIPS flexibilities such as patent oppositions, patentability criteria and the limitation of TRIPS plus measures such as patent term extensions. Given the capacity constraints the South African government may face in implementing the recommendation in its draft IP Policy calling for the substantive examination of patents, the sharing of experiences and the providing of

⁸⁰⁹ China, in Paragraph 284, of document WT/ACC/CHN/49 of 1 October 2001 agreed to six years of data exclusivity. The relevant portion of paragraph 284 notes that China agrees that:

"no person, other than the person who submitted such data, could, without the permission of the person who submitted the data, rely on such data in support of an application for product approval for a period of at least six years from the date on which China granted marketing approval to the person submitting the data."

⁸¹⁰ Russia in paragraph 1292 of document WT/ACC/RUS/70 makes a commitment similar to China's with the result that six years of data exclusivity are applicable.

⁸¹¹ According to Article 35 of the Implementing Regulations of the Drug Administration Law of 4 August 2002, China provides six years of data exclusivity as from the date of marketing approval. Russia also provides for six years of pharmaceutical data exclusivity through Article 18.6 of the "Law on Circulation of Medicines.

⁸¹² It is reported that the issuing of a compulsory license in Brazil for the ARV efavirenz in 2007 resulted in cost savings of approximately USD 237 million over five years. See UNAIDS, UNDP, WHO (2012) 'Using TRIPS flexibilities to improve access to treatment' [Online] Available at:

http://content.undp.org/go/cms-service/stream/asset/?asset_id=3259398

⁸¹³ More information on the proposed reforms including a letter written by academics and members of civil society is [Online] Available: <http://infojustice.org/support-brazil>

training by patent examiners from India and in particular could be an optimal example of south-south co-operation among two of the BRICS to further mutual aims and objectives.

South Africa is also a member of IBSA, a configuration including Brazil and India which was formed in 2003.⁸¹⁴ However, there has not been the same degree of formal co-operation between the leaders of IBSA on intellectual property and public health matters, with BRICS appearing to be the preferred configuration for inter-regional co-operation. The future of IBSA as a co-ordinating mechanism between its members was placed into doubt with the postponement of the sixth Heads of State summit scheduled to take place in New Delhi in June 2013.⁸¹⁵ No new date has emerged for the next summit, thus raising the question whether IBSA's days as a south-south co-operation mechanism are numbered.⁸¹⁶

6.4 Conclusion

As has been discussed above, there are several promising initiatives at the sub-regional, intra-regional, continental and inter-regional levels that may support countries in eastern and southern Africa to maintain and expand programmes to treat people living with various communicable and non-communicable diseases. These initiatives are well timed, given the decline in donor funding for AIDS in recent years, reflected most recently by the failure by the GFATM in December 2013 to meet its US\$ 15 billion target by US\$ 3 billion. The reform of intellectual property related legislation to better incorporate public health related TRIPS flexibilities has been taking place across more than a dozen countries in eastern and southern Africa in recent years. Both of these developments support the first hypothesis advanced in chapter one concerning the increased attention that must be paid to the integration and use of public health related TRIPS flexibilities in

⁸¹⁴ The first meeting of IBSA leaders was a foreign affairs ministers' meeting in June 2003 which took place in Brazil. The ministers signed a declaration pledging co-operation on several topics of mutual interest including UN reform, trade and investment, economic and social development as well as science and technology issues. The Declaration is [Online] Available: http://web.archive.org/web/20070915141009/http://www.ibsa-trilateral.org/brasil_declaration.htm

⁸¹⁵ See Delhi Business standard Newspaper Report of 20 March 2013 '*Summit in Delhi Put Off*' [Online] Available: http://www.business-standard.com/article/pti-stories/ibsa-summit-in-delhi-put-off-113052000878_1.html

⁸¹⁶ According to an online article by Stuenkel, O 4 July 2013 '*Is IBSA Dead?*' [Online] Available: <http://www.postwesternworld.com/2013/07/04/is-ibsa-dead/>. The writer points out, among other things, that the leaders of IBSA met at a BRICS summit in March 2013 and that a second summit 3 months later would have been unnecessary.

order to sustain national treatment programmes in the face of declining donor funding for AIDS responses.

It should also be recalled that while several countries have undertaken or are in the process of amending legislation to take greater advantage of public health related TRIPS flexibilities, many are yet to do so. For those countries that have taken steps to reform legislation, the results have been mixed for various reasons. These include the fact, as seen in South Africa, that there are competing interests advocating for the inclusion of different provisions. Another reason for the mixed legislative reform must be the often conflicting policy advice offered by the providers of technical and policy advice, a situation exacerbated by low levels of capacity in several government departments responsible for the administration of intellectual property as discussed in in chapter four and articulated in the second hypothesis of this thesis.

There are several initiatives underway in eastern and Southern Africa to foster south-south co-operation on treatment access, with the EAC's RPMPoA, having made the most progress. The SADC countries, albeit at a slower pace, have demonstrated political will to implement the SADC Pharmaceutical Business Plan. Care has been taken to ensure complementarity of regional initiatives with the AU's PMPA. However much of the promise south-south initiatives could hold for the acceleration of treatment access in the region may be undermined by some significant challenges. The first of these relates to the prioritization of local pharmaceutical production in the region. As noted above, at least 38 countries in Africa engage in some form of pharmaceutical manufacturing, with companies in South Africa and Egypt retaining the capacity to produce APIs. For African pharmaceutical producers to be competitive, harnessing the requisite economies of scale is a necessity. Given the importance being attached to the sustaining and scaling up of treatment programmes in Africa, it may be a politically untenable prospect for a country's leaders to choose to support a neighbour's pharmaceutical manufacturer at the cost of its own, particularly if the neighbouring manufacturer is not able to provide a pharmaceutical product at a price that is close to the internationally most competitive price.

Ultimately, the success or failure of regional co-operation initiatives on local pharmaceutical production will depend on the ability of local manufacturers pharmaceutical industries to make

safe and efficacious medicines of international quality and at an affordable price. As the example of Zimbabwe's Varichem Chemicals discussed in chapter three illustrates, a commitment by the continent's leaders to support viable pharmaceutical industries is an important determinant of success. Another important factor is the presence of a coherent and complementary legal and regulatory environment which fully incorporates public health related TRIPS flexibilities as is drug regulatory legislation which supports the production of safe and efficacious medicines of good quality.

Yet another important factor that could determine the success of promising initiatives is that of policy coherence. At present, these regional initiatives aimed at increasing co-operation on access to treatment risk being undermined by developments such as the proliferation of anti-counterfeiting legislation in certain EAC countries and within the EAC itself, the newly established PAIPO which appears to be more focused on intellectual property enforcement and protection than facilitating the use of TRIPS flexibilities as well as the Draft Preliminary Model Law on Medicines Regulation Harmonization which appears to impose some provisions on data exclusivity. An additional aspect of policy incoherence at the regional level is the misalignment between some provisions of the Harare Protocol as well as the practices of ARIPO patent examiners on the one hand, and the national legislation of those ARIPO Member States that have more extensively incorporated public health related flexibilities into national legislation such as Zanzibar and Uganda. The findings of this chapter therefore validate the third hypothesis advanced in chapter one, namely, that policy incoherence at the national and regional levels could undermine the incorporation and use of TRIPS flexibilities, thus bringing the sustainability of treatment programmes into question unless addressed.

Finally, it should be noted that important but as yet unrealised opportunities exist for countries within eastern and southern Africa to share examples of how the implementation of public health related TRIPS flexibilities have resulted in increased treatment access. One such example could be for South African competition law officials to highlight to other countries in the region how the Competition Act law has been used to sanction anti-competitive behaviour in the country. Similarly, opportunities exist for the large developing country partners such as Brazil and India to share examples with countries in eastern and southern African countries of how certain public

health related TRIPS flexibilities were employed to keep treatment costs affordable. One such example from India could be its implementation of Article 27(1) of the TRIPS Agreement through the enactment of Section 3(d) of the Patents Act of 2005. Training for South African and ARIPO patent examiners on the undertaking substantive pharmaceutical patent examinations from a public health sensitive perspective could be another useful south-south exchange example. A third example could be a south-south exchange between Brazilian officials and various national and regional government officials in eastern and southern Africa on the involvement of the drug regulatory authority in Brazil in the examination of pharmaceutical patents.

7 Concluding Reflections

“We can do things the cheap way, the simple way, for the short-term and without regard for the future. Or, we can make the extra effort, do the hard work, absorb the criticism and make decisions that will cause a better future.”

Mike Rounds

7.1 Background

As the previous six chapters have demonstrated, the public health related flexibilities present in the TRIPS Agreement are becoming of greater importance as countries in eastern and southern Africa re-examine their policy options available to sustain and expand various national treatment programmes. As discussed in chapter one, the revision of WHO treatment guidelines in June 2013 has increased the number of people eligible for ART to more than 21 million people by the end of 2013, the large majority of who live in Africa. While an impressive scale up in treatment has taken place in recent years, the reality remains that more people need ART than are currently receiving it in eastern and southern Africa.

As also discussed above, the large majority of patients on ART in sub-Saharan Africa are still on first-line ART, which as a result of generic competition and donor financing remain relatively affordable. However, the combination of drug resistance and the emergence of newer, less toxic and more effective medicines more likely to be patented in countries that have traditionally supplied generics will require more importing countries to incorporate public health related TRIPS flexibilities into national legislation. Moreover, the steady decline in multilateral aid for AIDS and health responses as discussed in chapters one, four and six, is an indication that countries in eastern and southern Africa will be expected to assume greater financial responsibility for national treatment programmes.

The hypotheses advanced in chapter one were the following: First, the incorporation of public health related TRIPS flexibilities into domestic legislation has not been a priority for countries in

eastern and southern Africa because most patients on ART are still on first-line ART regimens, which are both affordable, and funded by bilateral and multilateral donor institutions. However, TRIPS flexibilities will become more important as multilateral funding declines and treatment programmes require the greater use of more expensive new-generation ARVs increasingly being patented in countries with significant pharmaceutical manufacturing capacity in the region such as South Africa, and elsewhere. Second, there are capacity constraints within the relevant government departments in eastern and southern Africa which hinder the full integration of public health related TRIPS flexibilities into the relevant national legislation and the use of these flexibilities when needed. Third, while capacity constraints and a reliance on donor funding are both present, these two factors alone do not present a holistic picture of challenges in the region which are more complex than may appear. There is a significant degree of policy incoherence in the form of national level legislation and regional initiatives, which if not addressed by law reform and increased co-ordination could undermine the incorporation and use of TRIPS flexibilities in the national and regional level, thus bringing the sustainability of treatment programmes into question. The key findings of the country case studies and the prospects for south-south co-operation as postulated in the hypotheses follows below.

7.2 Key Findings for Tanzania and South Africa

The United Republic of Tanzania typifies the situation that many countries in eastern and southern Africa find themselves in at present. First, the country has seen a significant increase in the uptake of ART over the past decade. This development is tempered by the fact a large treatment gap remains. Moreover, as is the case with most countries in eastern and southern Africa, Tanzania remains heavily reliant on foreign donor assistance to finance its national HIV treatment programmes. While the local pharmaceutical industry in Mainland Tanzania is taking hold, it remains at a nascent stage and has not been able to compete for tenders financed by multilateral donor entities. It is likely that Tanzania can expect to remain an importer of newer generation ARVs particularly those used in second and third line ART for the foreseeable future.

South Africa finds itself in a position quite different from other countries in the region for two reasons. First, it self-finances the majority of its AIDS response and is less reliant on donor funding. Second, it is home to a generic pharmaceutical industry which includes one of the world's largest generic manufacturers Aspen Pharmacare among others. However, South Africa finds itself in a position similar to other countries in the region in embarking on significant intellectual property reform while exploring other measures including changes in government procurement practices all with the aim of achieving cost efficiencies.

As with countries in the region, legislative reform has been mixed in Tanzania. Zanzibar concluded the reform of its Industrial Property Act of 2008 and is regarded as a successful example of how public health related TRIPS flexibilities can be integrated into national legislation. Mainland Tanzania is also undergoing intellectual property law reform although it remains to be seen whether public health related flexibilities currently missing from Mainland Tanzania's Patent Act of 1987 will be incorporated into a new Act, and to what degree. The emergence of the first draft IP policy in South Africa, the ongoing reform of industrial property legislation in mainland Tanzania and the successful enactment of the Industrial Property Act in Zanzibar in 2008 in a manner that mostly incorporates key public health related TRIPS flexibilities validates the first hypothesis advanced in chapter one concerning the increased importance that countries in the region are attaching to the incorporation of public health related flexibilities into domestic legislation.

This thesis has also found that in a number of instances, countries in eastern and southern Africa continue to face significant, and in some cases, serious capacity constraints. These constraints have stymied the effective incorporation of public health related TRIPS flexibilities into national legislation. Mainland Tanzania has been undertaking industrial property law reform for several years, a situation that a number of countries in the region find themselves in. At present, mainland Tanzania has delayed the enactment of new intellectual property legislation until a policy has been finalized with the support of WIPO. As noted in chapter six, several countries in the region are reforming their laws with support from various bilateral and multilateral technical agencies. These reforms which have been ongoing for a number of years with the support of several bilateral and

multilateral organisations support the second hypothesis regarding the absence of sufficient national capacity on the public health aspects of intellectual property.

The challenges experienced by Zambia and Mozambique in attempting to issue compulsory licenses for ARVs whose patent status had not even been validated further underscores the capacity constraints the region has, and continues to face. Moreover, the patent offices of many countries in the region do not have the requisite capacity to examine patents and are therefore reliant on ARIPO to do so despite a misalignment between the operating statute of ARIPO and many national laws. Despite its complex framework of enabling legislation and the presence of many experienced professionals with experience in intellectual property management and administration, South Africa is not immune from the capacity constraints affecting other countries in the region. The draft IP policy of 2013 recommended that South Africa consider undertaking substantive patent examinations to reduce instances of ever-greening. This is likely to be an important factor into the ability of the South African Government to keep its national ART programme sustainable in the long term. Yet, as the country has never had a patent examination system, it currently does not have the requisite capacity to implement this important recommendation immediately.

This thesis has also demonstrated how policy incoherence at both the national and regional levels has hindered the development of a legal and policy framework required to sustain treatment in Tanzania. For political reasons, the country continues to retain two patent laws. While authorities in Zanzibar administer a patent Act that contains several public health related TRIPS flexibilities, the fact that Zanzibar's inhabitants constitute a fraction of the country's entire population, coupled with a comparatively low HIV prevalence, hinders Zanzibar's ability to employ public health related flexibilities to sustain treatment programmes. In order to achieve the requisite economies of scale needed to reduce treatment costs, is necessary for mainland Tanzania and Zanzibar to coordinate their use of public health related TRIPS flexibilities. The thesis has also demonstrated how regional initiatives such as the ambiguous draft anti-counterfeiting legislation could impede the availability of health technologies in the region. Another important example the thesis examines is how incoherence or misalignment between the enabling legislation and practices of

ARIPO and its members such as Tanzania could hinder a sustainable supply to more affordable health technologies.

One of the largest challenges facing South African authorities involved in legislative and policy reform remains the challenge of policy coherence. As discussed in chapter five, the actions of the various government departments whose activities relate to competition, intellectual property and the regulation of medicines shows a degree of discord among the various government departments, chief among them, the Department of Trade and Industry, the Department of Health, the Department of Science and Technology and the Department of Economic Development. The Department of Trade and Industry has stated its intention to reform the patent Act in a way that keeps treatment programmes sustainable. On the other hand, the same Department of Trade and Industry has stated ⁸¹⁷ support for PAIPO, an initiative led by the Department of Science and Technology which, from its draft enabling statute, appears to prioritize the protection of intellectual property above the sustainability of treatment programmes among others.

If the development of the draft PAIPO statute is any indication of co-operation between the various government departments responsible for the administration of various aspects of intellectual property, then the government's long term objectives to nurture a local pharmaceutical industry which innovates, while maintain the world's largest ART programme are cause for concern. The Department of Health, under whose ambit medicines legislation falls, and the Department of Economic Development under whose mandate the Competition Act is administered, should be actively involved in intellectual property policy and legislative reform undertaken by the Department of Trade and Industry.

As discussed in chapter one, the existing literature on the incorporation and use of public health related TRIPS flexibilities in eastern and southern African in almost all cases identifies capacity constraints, political pressure and inappropriate technical assistance as the primary reasons why more countries have not fully incorporated and used public health TRIPS flexibilities. Far less literature addresses the role of policy incoherence among the national and regional stakeholders in

⁸¹⁷ According to a media Statement by the South African Minister of Trade and Industry Rob Davies on 5 November 2013 [Online] Available: <http://www.thedti.gov.za/editmedia.jsp?id=2899>

perpetuating the current situation. The findings of this thesis in both country studies on the role of policy incoherence as a significant impediment in addition to other factors addressed in this thesis and elsewhere constitutes a modest contribution to a rich existing field of literature.

7.3 Prospects for South-south Co-operation on Health Technologies in Eastern and Southern Africa

Recent regional initiatives including the African Union's PMPA and accompanying Roadmap for shared Responsibility and Global Solidarity are further indications of a shift in responsibility from multilateral funding mechanisms to African governments as postulated by the first hypothesis.

As discussed at length in chapter six, there is an unprecedented focus on initiatives to increase south-south co-operation both within regional configurations in eastern and southern Africa and between blocs of countries in the region and large developing countries including India, China, Brazil and the BRICS configuration of countries. The EAC, with its RPMPoA and the draft Protocol on the TRIPS Agreement has made the largest strides towards regional co-operation. The political will to co-operate, combined with the EAC's relatively small membership of five Partner States, decades long history of regional co-operation, donor commitment and legislative reform on intellectual property in a number of countries increases the likelihood of successful co-operation among its Partner States. SADC, with its Pharmaceutical Business Plan has made important progress towards the joint procurement and intra-regional trade of essential medicines. However, its 15 country membership, three official languages, history of political as opposed to economic co-operation, diverse set of members at various levels of development and combination of civil and common law legal systems faces significantly more challenges in achieving the level of policy coherence required to benefit from pooled procurement and the free movement of health technologies.

Initiatives within the EAC and SADC as well as the AU Roadmap for Shared Responsibility and Global Solidarity may yet be undermined by a lack of policy coherence with the emergence of regional and national anti-counterfeiting legislation, an ARIPO Secretariat, whose previous actions

in granting pharmaceutical patents under a lax set of criteria appears to favour the protection of intellectual property rights over the increasing of access to new health technologies, and the creation of the PAIPO in 2013 which appears to promote the protection and enforcement of intellectual property above increasing access to health and agricultural commodities. For the initiatives at the EAC, SADC and AU level to meet their desired goal, a greater degree of coherence is needed between the various institutions involved in intellectual property norm making, standard setting and administration than presently occurs.

There is also potential for increased south-south co-operation on legal and policy matters through the partnerships between African countries on the one hand, and large developing countries with significant pharmaceutical manufacturing capacity and expertise such as India, Brazil and China on the other. A potential example of such co-operation could be the training of South African pharmaceutical patent examiners by Brazilian and Indian counterparts as part of a BRICS co-operation programme on intellectual property.

Finally, it bears recalling the assertions made in chapter one of the thesis: while the intellectual property related policy legislative framework are a key determinant of treatment sustainability, there are a number of factors outside the scope of this thesis which will ultimately determine the likelihood of success of several regional initiatives. These factors are both technical and political in scope. This thesis has examined the intellectual property related technical aspects. Political will on the part of the leaders of countries in the region is a key consideration. Policy makers may at times have to make politically unpopular decisions against the short term national interest, such as choosing to not support a local pharmaceutical industry which is uncompetitive, in favour of supporting a competing local pharmaceutical industry from a neighbouring country in order to generate economies of scale. At present, a number of regional initiatives have not resolved the tensions between the promotion of local pharmaceutical industries and the need to accelerate and sustain treatment access. The provision of sufficient incentives to innovators while ensuring that patients in eastern and southern Africa are able to access affordable health technologies remains a delicate balancing act, as is the case in developed and developing countries the world over.

Appendix One: Terminology

Low and Middle Income Countries

The term “low and middle income” originates from the World Bank Atlas method which is used to classify 188 countries who are members of the World Bank and 26 other economies with a population of exceeding 30 000 into four income groupings. The calculation is made on the basis of gross national income (GNI) per capita converted from local currency into US dollars. There are four country categories: low, lower-middle, upper middle and high income. Countries are re-evaluated on an annual basis and can be re-assigned to different categories every July. The current, the classifications are:

Country	Income level per annum
Low income	GNI of US\$ 1045 or less
Lower middle income	Between US\$ 1045 and US\$ 4125
Upper middle income	Between US\$ 4125 and US\$ 12 746
High income	US\$ 12 746 or higher

At present, 139 countries and economies are classified as LMICs, with 75 classified as high income countries. The World Bank classification has been criticised for relying solely on GNI as a factor for classification without consideration of other factors such as levels of industrialisation and inequality.

Developed, Developing and Least Developed Countries

The list of Least Developed Countries (LDCs) is determined on an annual basis by the United Nations (UN) Economic and Social Council and the factors considered include the GNI per capita, an index of human assets and an economic vulnerability index. In December 2013, 48 countries

were classified as LDCs although Equatorial Guinea and Vanuatu are to graduate from their LDC status by June and December 2017 respectively.

On the other hand, there is no universally accepted definition of developing and developed countries. The most widely used definition originates from the International Monetary Fund (IMF) which lists 42 UN Member States as developed, a further 18 countries comprising predominantly of the former Soviet Union and Yugoslavia as economies in transition, and more than 140 countries as developing countries. Developed countries are considered to have a comparatively high living standard, level of industrialization and a high ranking on the United Nations Human Development Index (HDI) which ranks countries on the basis of education levels, life expectancy at birth and income levels. Developing countries on the other hand are categorised by their generally lower ranking on the HDI, and comparatively lower levels of industrialisation and lower living standards. All countries in the eastern and southern African region are listed either as developing countries or LDCs.

Eastern and Southern African Countries

There is no commonly accepted list of countries that can be classified as eastern and southern African. However, for the purposes of this thesis, countries regarded as being part of the regional economic communities including the five East African Community (EAC) Partner States, the 15 Member States of the Southern African Development Community (SADC) as well as the countries of Djibouti, Eritrea, Ethiopia, Somalia and South Sudan are regarded as eastern and southern Africa countries.

Essential Medicines, Essential Drugs, Pharmaceutical Technologies and Health Technologies

For the purposes of this thesis, the term essential drugs, essential medicines and pharmaceutical technologies are used interchangeably. Essential medicines refer to the list of medicines defined by the World Health Organization (WHO) as satisfying the priority health care needs of a population. They are selected with consideration to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Health technologies are a more widely encompassing

group and for the purposes of this thesis include vaccines, diagnostics, medicines and medical devices.

South-south co-operation

South-south co-operation entails collaboration between two or more countries, and occurs on a bilateral, regional, sub-regional or interregional basis as some of the examples below. Exchanges tend to revolve around the exchange of knowledge, skills, expertise and resources to meet their development goals. In the context of access to treatment, it refers to technical co-operation between developing countries to meet common development objectives as first formalized at a meeting of UN Member States in Buenos Aires in 1978.

Appendix Two: Recommendations on TRIPS flexibilities in EAC TRIPS policy document

TRIPS Flexibilities	Recommendations from the EAC Policy on intellectual property
Transitional periods	<ul style="list-style-type: none"> • All EAC Partner States that are LDCs are to take advantage of the 2016 transition period and provide in their national patent laws for a further extension of this period as may be agreed upon by the Council for TRIPS. • All EAC Partner States are to abolish any ‘mailbox’ provision in their existing or draft national patent laws.
Article 31 of TRIPS	<ul style="list-style-type: none"> • Limit remuneration to the UNDP recommended figure of 4% maximum, and take anti-competitive behaviour into account when determining the amount of remuneration; • Include in their patent laws a maximum period of 90 days for prior negotiations; • Specify all four situations where prior negotiations can be waived, namely, national emergencies, situations of extreme urgency, public non-commercial use and to remedy anti-competitive behaviour of the patent holder; • Exclude injunctive relief as a remedy available under independent review of government use licences; • Authorise administrative entities to grant all kinds of compulsory licenses;
Patentability criteria	<ul style="list-style-type: none"> • Strictly define in the patent laws and/or patent examination guidelines the patentability criteria, and apply them strictly, in order to keep a broad public domain. • Strictly apply the novelty standard through considering a wide concept of prior art • Define the inventive step standard by referring to a ‘highly’ skilled person;

	<ul style="list-style-type: none"> • Strictly apply the industrial application requirement.
Parallel importation	<ul style="list-style-type: none"> • Adopt an international exhaustion of rights system across all forms of IP
General exceptions to patentability	<ul style="list-style-type: none"> • Explicitly authorise the Bolar exemption for activities reasonably related to research and development or marketing approval • Explicitly authorise research for scientific, non-commercial and commercial purposes • Provide a right to claim a non-exclusive licence for the use of patented research tools against payment of compensation.
Interpreting Article 39.3 on test data protection	<ul style="list-style-type: none"> • Kenya as the only non LDC Partner of the EAC should adopt a system to protect test and other data against unfair commercial use and disclosure, while leaving the drug regulatory authority to rely on the results of original test data from domestic or foreign approvals when assessing the safety and efficacy of generic competing products. • None of the EAC Partner States may establish a linkage between patent protection and marketing authorisation, which would prevent MRAs from granting marketing approval for generic medicines before the end of the patent term
Anti-competitive remedies	<ul style="list-style-type: none"> • Provide for remedies to patent right abuse, such as compulsory licences.
30 August 2003 Mechanism	<ul style="list-style-type: none"> • Amend compulsory licensing provisions to authorise the export of up to 100% of pharmaceutical production to countries with insufficient pharmaceutical capacities • Draft guidelines both as exporting and importing countries on the export/importation of pharmaceutical products into countries with insufficient pharmaceutical manufacturing capacities under the 30 August 2003 Agreement

Appendix Three: List of Interviewees (on a non-attributable basis)

1. Researcher for a Geneva based civil society organisation
2. Official working for a Geneva based inter-governmental organisation
3. Civil society representative from Uganda
4. Patent examiner from Zambia
5. Health official from the East African Community
6. Officials from BRELA
7. Official from COSTECH
8. Local pharmaceutical manufacturer in Tanzania
9. Official from TFDA
10. Official from Registrar General's Office in Zanzibar
11. Official from Department of Trade and Industry in South Africa
12. Official from Department of Health in South Africa
13. Official from African Union
14. Expert familiar with the PMPA
15. Official from Department of Economic Development in South Africa
16. South African Patent Attorney

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